Project number: 120 72.761.01
Project title: Risico-inventarisatie verpakkingsmateriaal

Project leader: L.W.D. van Raamsdonk

Report 2011.002 March 2011

A risk evaluation of traces of packaging materials in former food products intended as feed materials

L.W.D. van Raamsdonk[1], R. Rijk[2], G.P.J. Schouten[3], W. Mennes[4], G.A.L. Meijer[5], A.F.B. van der Poel[5], and J. de Jong[1]

[1] **RIKILT – Institute of Food Safety**
Wageningen University and Research centre
Akkermaalsbos 2, 6708 WB Wageningen
P.O. Box 230, 6700 AE Wageningen
The Netherlands
Tel +31 317 480 256
Fax +31 317 417 717
Internet www.rikilt.wur.nl

[2] Agency for Food Packaging Materials
[3] Schouten Advies B.V.
[4] Dutch National Institute for Public Health and the Environment (RIVM)
[5] Animal Sciences Group (WUR)

Distribution list:

- Ministry of Economic Affairs, Agriculture and Innovation (EL&I); drs. E.R. Deckers.
- Food and Consumer Product Safety Authority (nVWA); drs. W. Ooms, dr. R. Theelen, mr. drs. R. Herbes.

Summary

The elaboration of a ban on packaging materials in former food products intended as feed material needs, at least in part, to be based on a proper risk assessment. The current project provides information to be able to carry out a risk *evaluation* as first step to establish a risk *assessment*.
In addition to the assignment of the Dutch Competent Authority, focus is on the European perspective of the European Commission, the European Food Safety Authority and the European Parliament. Regulation (EC) 767/2009 provides the following ban: "List of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited as referred to in Article 6. [points 1-6] 7. Packaging from the use of products from the agri-food industry, and parts thereof." A proper risk assessment is considered pivotal as basis for a legal and biological underpinning, and for a proper interpretation of this prohibition.

In the Netherlands a major category of former food products is processed consisting of 300 000 MT of bakery products, and minor shares of cocoa products and sweets (as syrups). The bakery products are predominantly intended as feed material for pig feeds. Especially the sweet syrups are applied as replacer of molasses in all kind of compound feeds.

A total of 243 samples were investigated in the Dutch monitoring program for feed materials (2005-2010). In the 160 included samples of bakery products an annual average between 0.03 % w/w and 0.06 % w/w was found. More than 90 % of all samples investigated showed a level of presumed residuals of packaging materials below a threshold of 0.15 % w/w. For the category of bakery products more than 95 % of the samples remained under the level of 0.15 % w/w. The selected particles are indicated as "presumed residuals of packaging materials" since it is not possible to formally identify these particles afterwards as originating from the original packaging material.

Risks for animals, humans and for the environment are evaluated. These risks are extensively discussed in the report. Above that, a Failure Mode and Effect Analysis has been carried out in order to provide a relative ranking of the identified risks. The highest relative priority number (RPN) resulting from the analysis is 6 (for printing inks) on a scale between zero and 27. It was concluded that paper and board as matrix show a reasonable good digestibility, which results in the absence of risk at the contamination levels found. The situation for plastic is more complex. The risks that need more attention are as follows:

Animal risks: the risks with the highest RPN are additives in printing inks, aluminium and softeners in regenerated cellulose. The values for these RPNs are generally caused by a scarcity of relevant data, and a worst case scenario is applied. In practice the risk for printing inks will be lower than indicated, since the share of the printed area of the total surface is less than 100 %. A large range of additives can be present in packaging materials. According to European legislation, these additives are exclusively tolerated after prove of either a low toxicity or a low migration from the packaging material to the food. Even in the situation that these additives might show a high migration under the circumstances of the gastro-intestinal tract of animals, only a limited risk is to be expected at the low contamination levels found. A further risk assessment in view of the occasional presence of packaging materials and monitoring of selected compounds (e.g. aluminium) could be recommended. Physical risks are almost absent.

Human risks: the risks of exposure to chemical compounds from packaging materials via the animal feed route is generally low. The long half-life of aluminium in animal tissues is a matter of concern. Physical risks are absent by definition.

Environmental risks: the risks for the environment are very difficult to specify. The deposition of low density polyethylene (LDPE) as a type of plastic reaches notable levels. A worst case calculation of the exposure of LDPE to the environment by means of pig manure results in an amount of 71 kg/km^2 per annum. Provided its low degradability, a steady state level can reach 5000 kg/km^2 . This seems reasonable, but the annual deposit to the "plastic islands" in the oceans is estimated at a level of 5 kg/km^2 per annum. This comparison indicates that an assessment of risk might be elaborate, but desired.

It is recommended to assess more thoroughly the level of risk for the aspects mentioned.

On the basis of the evaluation in this study of packaging materials in FFP intended for animal feed, the following four aspects can be pointed out:

- The evaluated risks are limited; further attention is required for the specific risks as mentioned in the previous paragraph.
- The European Union maintains an extended policy for accepting packaging materials.
- Unpacking procedures for former food products are well established and maintained.
- A tolerance limit higher than zero can sufficiently be monitored by means of the existing control method for the category of former food products with the largest annually produced amount (i.e. bakery products).

Considering these aspects, and in the view of the limitations of the current study, it can be concluded that major animal or human health risks have not emerged from the current evaluation, but that for some (components of) packaging materials only very limited data is available. A tolerance level higher than zero could be acceptable, whereas some aspects need further considerations to conclude a specified value. It may be considered to establish different tolerance levels for the different types of former food products.

It can be considered a waste of highly nutritional material when former food products are not used as ingredient of animal feed. At the same time any unreasonable exposure of farmed animals to remnants of packaging materials should be avoided.

Samenvatting

De invulling van een verbod op verpakkingsmateriaal in voormalige voedingsmiddelen bedoeld voor diervoeding dient, ten minste ten dele, gebaseerd te zijn op een goede risicobeoordeling. Het onderhavige project geeft antwoord op de behoefte om via een risico-*evaluatie* een aanzet te geven tot een risico*beoordeling*. Daarbij wordt gelet op de vraagstelling van de Nederlands competente autoriteit, met aandacht voor het Europese perspectief van de Europese Commissie, de Europese Voedselveiligheid Autoriteit en het Europese Parlement.
Verordening (EG) 767/2009 geeft het volgende verbod: "Lijst van middelen waarvan het in de handel brengen of het gebruik als diervoeding als bedoeld in artikel 6 aan beperkingen onderhevig of verboden is: [punten 1 – 6] 7. Verpakkingen en delen van verpakkingen afkomstig van het gebruik van producten van de voedingsmiddelenindustrie." Een goede risicobeoordeling is essentieel als basis voor een goede juridische en biologische onderbouwing, en voor een goede interpretatie van dit verbod.

In Nederland is sprake van een hoofdstroom voormalige voedingsmiddelen van ca. 300.000 ton per jaar aan bakkerijproducten, en kleinere stromen van chocoladeproducten en snoepsiroop. De bakkerijproducten worden vooral verwerkt in varkensvoeders, terwijl met name de snoepsiroop wordt gebruikt als vervanger van melasse voor het pelleteren van allerlei soorten voeder.

In het Nederlandse monitoringsprogramma (2005-2010) zijn in totaal 243 monsters geanalyseerd. In de 160 monsters bakkerijproducten werd tussen 0,03% w/w en 0,06% w/w vreemde bestanddelen gevonden. In totaal is het gehalte aan vreemde bestanddelen bij meer dan 90% van alle monsters minder dan 0,15% w/w. Voor de categorie bakkerijproducten blijft meer dan 95 % onder het niveau van 0,15 % w/w. Hier is sprake van de aanwezigheid van "vreemde bestanddelen", omdat achteraf niet kan worden vastgesteld of er formeel sprake is van het oorspronkelijk verpakkingsmateriaal.

Risico's voor dier, mens en milieu zijn geïnventariseerd. Deze risico's worden in het rapport uitgebreid besproken. Daarnaast is een Failure Mode and Effect Analysis uitgevoerd om een aantal risico's die kunnen optreden te kunnen ordenen op ernst. Het hoogste risicogetal uit de huidige analyse is 6 (voor drukinkt) op een schaal van nul tot 27. Er kon worden vastgesteld dat papier en karton als drager een redelijke tot goede verteerbaarheid hebben, en daardoor geen risico vormen bij de aangetoonde gehaltes. Voor plastic is de situatie meer complex. Risico's die binnen de gevonden risiconiveaus dan nog verdere aandacht verdienen, zijn:

Dier: componenten uit drukinkten, aluminium en weekmakers in geregeneerd cellulose. Deze aanduidingen komen vooral voort uit het feit dat er weinig informatie beschikbaar is en daarom een worst case aanname wordt gehanteerd. In de praktijk zal met name een risico door drukinkten aanzienlijk lager liggen omdat het percentage bedrukking ver beneden 100% van de totale oppervlakte ligt. Er kunnen een groot aantal additieven aanwezig zijn in plastic verpakkingsmateriaal, die volgens EU wetgeving alleen mogen worden toegepast bij een aantoonbaar lage toxiciteit, dan wel een aantoonbaar lage migratie naar voeding of voedingssimulanten. Zelfs als deze additieven onder omstandigheden in het maag-darmkanaal van dieren een aanzienlijk hogere migratie zouden vertonen dan naar voeding of simulanten, dan nog zijn risico's voor mens en dier niet aannemelijk bij de gevonden gehalten aan "vreemde bestanddelen". Een verdere uitwerking van mogelijke risico's en het

meten van niveaus van geselecteerde componenten (bijv. aluminium) is gewenst. Fysische risico's van verpakkingsmateriaal uit voormalige voedingsmiddelen zijn niet aan de orde.

Mens: bij een lage migratie vanuit de diervoeding naar dierlijke weefsels en producten zal de overdracht naar humane voeding eveneens laag zijn. Aandacht wordt wel gevraagd voor aluminium vanwege de mogelijkheid van overdracht in de humane voedselketen door de betrekkelijk lange half-waarde tijd. Fysische risico's zijn per definitie afwezig.

Milieu: De milieurisico's zijn complex. Er is een casus uitgewerkt met low density polyethyleen (LDPE). Een berekening van de blootstelling vanuit uitgereden varkensmest leidt tot een hoeveelheid van ca. 71 kg/km^2 per jaar. Gezien de lage afbreekbaarheid kan een langjarig evenwichtsniveau oplopen tot ruim 5000 kg/km^2 . Dit is bij een verdeling over een bodemlaag van 20 cm een gehalte van 0.0025% w/w LDPE. Dit lijkt laag, maar een aanvoer van ca. 71 kg/km^2 per jaar is veel hoger dan bij de "plastic eilanden" in enkele oceanen (geschat op ca. 5 kg/km^2 jaar). Deze vergelijking geeft aan dat een beoordeling van de risico's veelomvattend, maar gewenst is.

Op basis van de hier uitgevoerde eerste inventarisatie van mogelijke risico's van resten verpakkings-materialen in voormalige voedingsmiddelen kunnen de volgende factoren worden vastgesteld:

- De geïnventariseerde risico's zijn beperkt; aandacht wordt gevraagd voor enkele aspecten zoals boven uiteengezet.
- Er is een uitgebreid EU toelatingsbeleid voor verpakkingsmateriaal.
- Uitpakken wordt uitgevoerd door controleerbare processen.
- Een tolerantiegrens hoger dan nul kan goed worden gecontroleerd d.m.v. een gevalideerde kwantitatieve meetmethode voor de grootste stroom (bakkerijproducten).

Vanuit deze vaststelling kan de conclusie worden getrokken, met inachtneming van de beperkingen van deze studie, dat grote risico's voor de gezondheid van dier en mens niet gevonden zijn in de huidige studie. Voor sommige verpakkingsmaterialen of toevoegingsmiddelen is weinig informatie beschikbaar. Een tolerantieniveau hoger dan nul zou redelijk zijn, waarbij de tolerantielimiet vast gesteld kan worden op basis van een uitgebreide en formele risicobeoordeling. Overwogen kan worden om per type voormalig voedingsmiddel een apart tolerantieniveau in te stellen.

Uit oogpunt van duurzaamheid is het wenselijk om een optimaal waardevolle bestemming te geven aan producten (hier: voormalige voedingsmiddelen) voor diervoeding. Tegelijkertijd moet elke onredelijke blootstelling van landbouwhuisdieren aan resten verpakkingsmaterialen voorkomen worden.

Abbreviations

ALARA	As low as reasonable achievable
BFaN	German Federal Association for By-products as Animal Feed (Bundesverband für die Herstellung von Einzel- und Misch-Futtermitteln aus Nebenproducten der Nahrungsmittelindustrie)
BMELV	German Federal Minisitry of Food, Agriculture and Consumer Protection (Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz
BfR	German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung)
Da	Dalton
DG-SANCO	Directorate General for Health & Consumers, part of European Union
DM	dry matter
EL&I	Dutch Ministry of Economic Affairs, Agriculture and Innovation; formerly Ministry of Agriculture, Nature and Food Quality
FCM	Food Contact Material
FMEA	Failure Mode and Effect Analysis
FFPs	former foods products
FVO	Food and Veterinary Office, an agency of the European Commission
GI-tract	gastro-intestinal tract
HACCP	Hazard Analysis Critical Control Point
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LDPE	low density polyethylene
MT	metric ton
ND	not detectable
nVWA	Dutch new Food and Consumer Product Safety Authority (nieuwe Voedsel en Waren Autoriteit
OML	overall migration limit
PET	polyethylene terephthalate and copolymers
PO	polyolefins, including polypropylene and polyethylene
PS	polystyrene
pTWI	Provisionally Tolerable Weekly Intake
PVC	rigid polyvinylchloride
QM	maximum quantity in material
QMA	maximum quantity in $6 dm^2$ of material
RC	regenerated cellulose
Ref No	Reference number for substances listed in Directive 2002/72/EC
RIVM	(Dutch) National Institute for Public Health and the Environment (RijksInstituut voor Volksgezondheid en Milieu)
RPN	risk priority number
SCFCAH	Standing Committee on the Food Chain and Animal Health, a committee of the European Union
SML	specific migration limit

Contents

1 Introduction

The consumption of a diverse range of food products, and with an optimal daily quality is an intrinsic part of our life. The demand for high food quality standards is a logical factor in the basic requirement for the quality of life: good food for health, targeted supply for children and elderly and a wide variety of diet foods which are readily availability. This demand also has important consequences. Food products should not exceed the declared shelf-lives. As a result, a lot of food products have to be removed from shops before being sold. Also earlier in the food production chain specific demands for quality and excess in production exist due to problems of manufacturing, packaging defects etc. The foods which are removed from the regular food chain for economic and quality reasons can be indicated as former food products (FFPs). This indication will be used throughout this report.

The long term aim for the society is the demand for sustainability. The unavoidable overproduction of food chain by-products compels to consider optimal application, use as feed material a.o., for ethical and economic reasons. Alternative use depends on the type, nature and quality of the FFPs. It is impossible and unwanted to apply one general strategy to these FFPs, since one general "group of FFPs" does not exist. A strategic diversification of alternative uses is required.
Prerequisites for any alternative use are a minimalisation of risk and a maximum valorisation. As a framework for alternatives, the so-called 'Ladder of Moerman' (an analogy to Lansink's waste ladder as used in waste management) can be applied (figure 1; [1, 2]). Dumping and burning of FFPs do hardly result in any economic value, and risk might exist in terms of effect on nature management and of climate change if no further precautions are taken. At the opposite, prevention of overproduction or reuse of FFPs in the framework of food banks has clear consequences in terms of ethical considerations or demands of society. The use of FFPs for biofuel production or recycling as ingredients of animal feeds might be a suitable solution to meet both ethical desires and economic effects. It can be expected that these two latter alternatives are different in terms of risk. Therefore, these risks have to be evaluated separately.

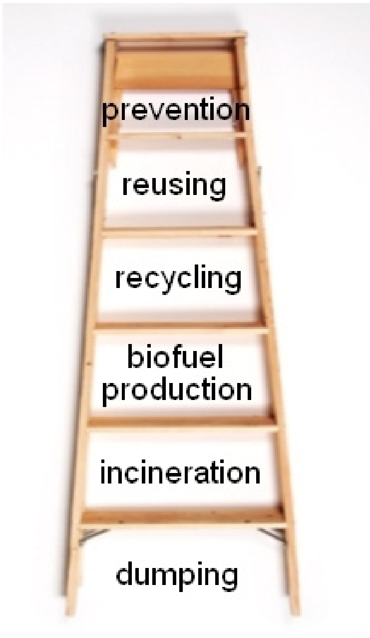

Figure 1: Ladder of Moerman, modified for former food products of the food production chain. For explanation see text.

In the current practice of food production, proper packaging of materials is provided for assuring quality maintenance during transport and storage. Besides the problem how to deal with packaging materials or remains thereof when reusing FFPs, other aspects have to be taken into account, such as the microbiological quality and the prohibition of animal proteins in animal feeds. Article 6 of Regulation (EC) 767/2009 of the European Parliament and of the Council of 13 July 2009 , states that: "Feed shall not contain or consist of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited". In Annex III of this Regulation, packaging from the use of products from the agri-food industry, and parts thereof are mentioned as prohibited for placing on the market or use for animal nutritional purposes (see Annex 1 to the this document).

Although there is a prohibition on the use of packaging materials in animal feeds, there is still an ambition to use certain types of unpacked and processed FFPs for this purpose. The German Federal Minisitry of Food, Agriculture and Consumer Protection (Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz; BMELV) acknowledged this ambition and asked early 2005 the Veterinary School in Hannover to carry out a risk assessment of FFPs. The results of this assessment have been published in August 2005 (Kamphues, 2005). The main conclusion of the report indicates that contamination levels of up to 0.15% w/w are deemed unavoidable in bakery products. A tolerance level of 0.125 % w/w should not result in significant risks (Kamphues, 2005).
The Dutch Ministry of Economic Affairs, Agriculture and Innovation (EL&I; formerly Ministry of Agriculture, Nature and Food Quality) and the Dutch Food and Consumer Product Safety Authority (nVWA, formerly VWA) paid attention to the conflict of interest between economic and ethical considerations for several years. In 2006 the VWA requested an evaluation of the German risk assessment made in 2005 from the Front Office Food Safety, a cooperation between the National Institute for Public Health and the Environment (RIVM) and RIKILT – Institute of Food Safety (see Annex 2 and 3). A further and more detailed risk assessment was recommended in the letter from VWA to the Ministry of LNV (Annex 2). Therefore, an additional evaluation should determine whether the usual levels of packaging materials after applying the ALARA principle meet the necessary requirement of minimal risk.

The Ministry of EL&I funded a short term pilot project for the inventory of major FFPs intended as feed material, for an inventory of packaging materials and an evaluation of the effects on animals, humans and the environment. This report presents the procedure followed, the results of the inventories and evaluation, and the conclusions and recommendations for future prospects. It is not the intention of the project to carry out a full risk *assessment* of all relevant aspects, but to present a compact risk *evaluation*, which can be used as a basis for identification of needs for further research.

2 Procedure of the study

2.1 Scope

The assignment of the project was to evaluate the risks of remnants of packaging materials in FFPs intended for use as ingredient in animal feeds. "Risk" in this report is defined as the product of three elements: the frequency of an incidence, the severity of an incidence, and the final impact on animal health, human health and the environment.

Apart from possible remnants of packaging materials, other circumstances or risks are important to decide on the usability of FFPs in feed. These include microbiological quality and digestibility. The presence, and if any, the amount of remnants of packaging materials is only one factor in the decision of a final application.

Included in this study are the FFPs of the food production chain that can be used as a feed ingredient after unpacking and processing. The processes of unpacking (see Chapter 3.4) can result in the presence of fragments of packaging materials. Within this focus on FFPs in a proper sense, several prerequisites are necessary to be made since the relevant FFPs are diverse. These prerequisites are:

- Some FFPs enter the market in a considerable larger amount than others. Only FFPs with a substantial quantity are worthwhile to consider in the current pilot study.
- The animal species to which the FFPs are intended to be fed is important. Ruminants and pigs response differently to certain materials because of their different physiology, gut function and diet preferences.
- Although FFPs are basically suitable for pets and fur animals, the application to these animals is excluded from the evaluation. Practice shows that due to several reasons the use of FFPs in the feeding of pets and fur animals hardly exists.
- Dairy products, wet as well as powders, can be used as feed ingredient for certain purposes. These products are included.

The scope on feed excludes other applications of FFPs such as production of biofuel, fermentation or composting. The types of FFPs excluded in this study for these reasons are:

- Mixed returns from retail. These products generally have a low nutritional value and often contain animal proteins, which are prohibited for feed. The sorting and unpacking of these flows are too costly.
- FFPs containing prohibited animal materials as intended in Regulation (EC) No 999/2001 and Regulation (EC) No 1774/2002 (meat, fish, salads).
- High moist and degradable products such as fruits, vegetables etc. with a low nutritional value.
- Products with a high oil of fat content such as butter, margarine, vegetable oil, sauces (these flows are generally processed to bio-fuels).

Furthermore, products such as catering waste (article 22 in Regulation (EC) 1774/2002) and frying fat as part of household waste (Annex in Decision 2004/217/EC) are prohibited to be used anywhere in the food production chain. Some feed ingredients like additives and other small ingredients as dairy products are supplied to the compound feed industry in bags. Since these products are not defined as FFPs, these are excluded from the study.

The scope as described implies that only a subset of the chemical compounds, which can be present in packaging materials, or which are described in Directive 2002/72/EC, are relevant for the current evaluation.

The elements included in this study range from an inventory of the types of FFPs and of the packaging materials to an evaluation of chemical and physical risks for animals, humans and the environment. The logical relationship between these elements is illustrated in Figure 2.

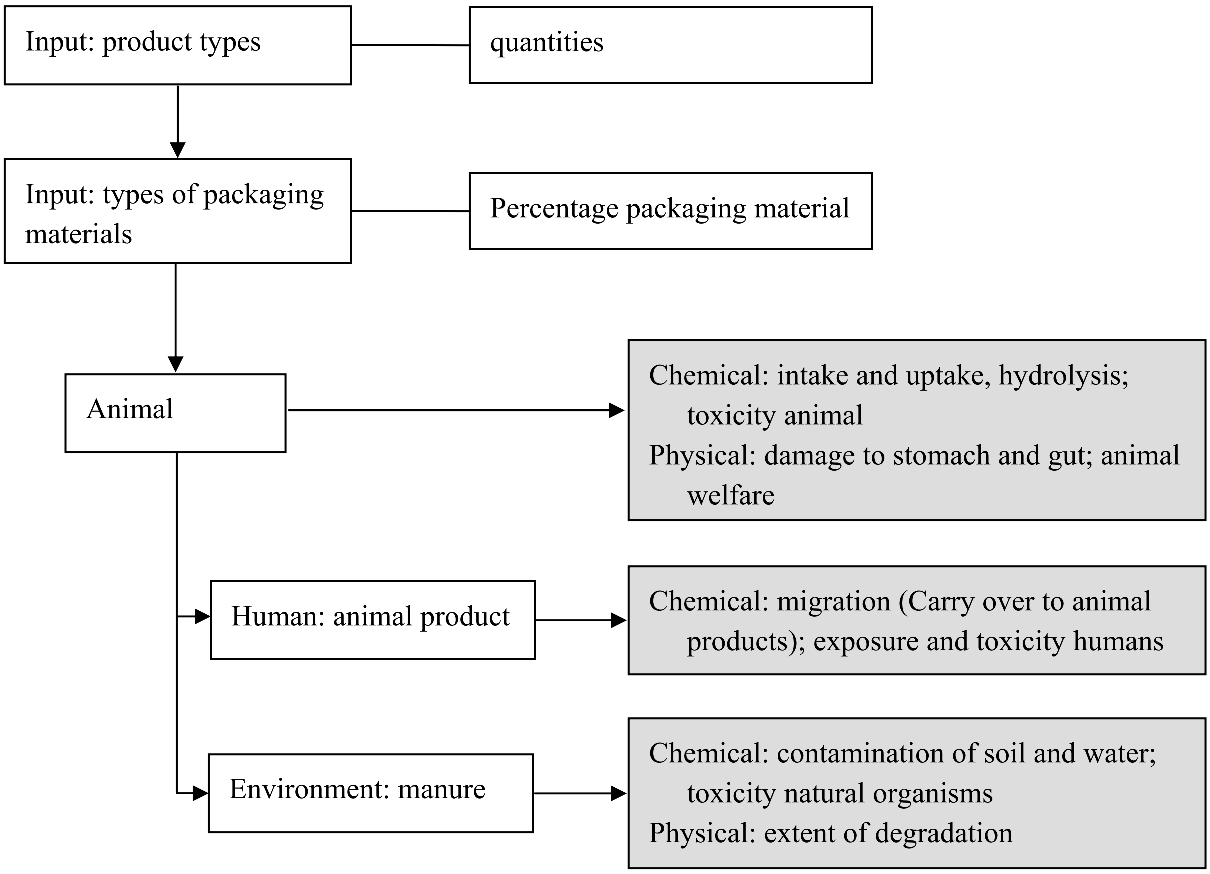

Figure 2. Outline of the current study. The inventory and evaluation includes the establishment and the types of FFP and their quantities, and the types of packaging materials found with their share in the FFPs. After animal consumption the chemical and physical risks for animals are evaluated. The effects on humans (consumption of animal products) and on the environment (manure as fertilizer) will be addressed.

2.2 Procedure

An inventory of useful methods for risk analysis and a framework for application in feed safety research was worked out in a Dutch project in 2006 (van Raamsdonk et al., 2007). From these methods the Failure Mode and Effect Analysis (FMEA) was selected for the current study, since it allows to rank risks with several causes in order of severity. A lot of basic information is not readily available to carry out an FMEA. Therefore, an expert panel was organised to collect information from several expertise fields.

An FMEA is based on the scaling of three parameters for each failure: severity, occurrence and detection (Stamatis, 2003; [3]). A failure can be identified as a risk in terms of the present study. Risks are aspects of the physical and chemical exposure by packaging materials of animals, human beings and environment. The three parameters are indicated by a factor on a numerical scale, e.g. from zero to five. Every risk will get a risk priority number (RPN) by the multiplication of the three factors. In this example of a scale between zero and five, an RPN ranges from zero to 125. RPNs are thus principally relative to each other, and the order of the resulting RPNs depends on the basic information for the estimation of the parameters and on the definition of the scales. As a consequence, the choice of experts for the collection of the information is vital for any reasonable result of the study. Some elements of Hazard Analysis Critical Control Point or HACCP are comparable to FMEA.
So-called "what-if" analyses are carried out for two different aspects. The way of implementation in this study includes the fixation of several values for a key parameters and the calculation of results in each of these cases. The comparison of the results reveals information on *what* will happen *if* a certain value is chosen.
The information as presented and used in this report was collected from a variety of sources: books, scientific papers, official publications of the European Union (legislation, opinions, risk assessments), internet sources and from networks of the experts. Literature references are given in the usual way. References to internet are presented in a separate paragraph in a numbered list and quoted in the text between square brackets [#]. All internet links are valid as of the date stated with the reference. Some Annexes contain their own lists of references.

2.3 Expert team

The following scientists were member of the project group (in alphabetical order):

- J. de Jong, analytical chemist, program leader animal feed, Statutory Tasks Program RIKILT (WUR): general support of the study.
- G.A.L. Meijer, nutritionist, project leader animal feed, Animal Sciences Group (WUR): environmental issues, coaching of process.
- W. Mennes, toxicologist, Dutch National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu (RIVM)): toxicology, risk evaluation.
- A.F.B. van der Poel, nutritionist, associate professor Animal Nutrition (WUR): physical risks, process technology.
- L.W.D. van Raamsdonk, biologist, senior scientist visual inspection methods, quality assurance, RIKILT (WUR): project leader, monitoring program results, FMEA risk evaluation.
- R. Rijk, director agency for food packaging materials: evaluation packaging materials, risk evaluation.
- G.P.J. Schouten, director consultant agency Schouten Advies BV for quality management in the food sector: inventory product types and application, process technology.

2.4 Timeframe

The project was initiated in the Spring of 2010. The expert group was organised in the Summer of 2010. During October, November and December 2010 the group met three times. During these meetings a range of aspects were discussed, the first drafts of the experts opinions were commented and the first draft of the final report was discussed. The report was finalised in March 2011.

3 Study overview and evaluation

The results of the study cover any of the aspects as illustrated in Figure 2. An inventory of background, types of materials and types of packaging materials are the basis for an overview and evaluation of the risks for animals, humans and the environment. These several aspects are presented and discussed in the following paragraphs.

3.1 Background

Packaging materials are not accepted as a feed ingredient according to Regulation (EC) No 767/2009 (see Annex 1), which prohibits the placing on the market or use for animal nutritional purposes of packaging materials from the agri-food industry for animal feeding. The legal interpretation of this regulation is not clear, ranging from the prohibition of any remnant of packaging material to a prohibition of *intentional* use. Recent evaluations of the practice in several EU member states by the EU Food and Veterinary Office (FVO) revealed the following situation:

- United Kingdom (mission June 2009): The national authority did not reach a conclusion on an acceptable tolerance level. An operator set a tolerance level of 200 cm^2 per 10 liters of product. The products examined reveal remnants of packaging materials, even larger than 10 cm in some cases. The official authority replies that they fully recognise the importance of this issue. Initiatives will be taken for inspections, stakeholder meetings and participation in the discussion at DG-SANCO.
- Germany (mission September 2009): The FVO mission team took notice of the German Bundesinstitut für Risicobewertung (BfR) opinion that a level up to 0.2% w/w of packaging materials in feed would not pose any risk to animals. The practice to allow FFPs with lower amounts but higher than zero is questioned on the basis of Decision 2004/217/EC. Overall, at national level, 3,454 analyses were performed for the presence of prohibited materials in feed (314% of the target set). The BMEVL replied that a risk assessment by the European Food Safety Authority (EFSA) is recommended. In the mean time all parties will apply all relevant procedures to ensure that any packaging materials in excess of 0.2% w/w are avoided.
- Ireland (mission September 2009): no tolerance limit was set by the authority, but an informal tolerance level of 0.25% w/w of a local recycler was accepted. Official samples were taken at an ad-hoc basis. The authority replied that they will modify their monitoring program, and awaits the results of the discussion of the Standing Committee on the Food Chain and Animal Health (SCFCAH) – Animan Nutriton, and the results of the EFSA opinion as requested by the Commission.
- Denmark (mission October 2009): a monitoring program was in place. Plastic wrapping appeared to be effectively removed, but paper remained present in one occasion. The authority replied that companies will be ordered to review their risk analysis and will take provisions to avoid paper materials.
- Belgium (mission April 2010): A specific tolerance level was not fixed by the authority. A number of 25 samples were taken in 2009 by the official authority for examining residues of plastic or metal. These samples were exclusively taken at farms. A private laboratory

performed checks on plastic and metal particles larger than 1 mm. In both procedures no residues were detected. The presence of paper was not examined. The competent authority replied that they plan to take samples from producers and will modify the examination method.

The new Dutch Food and Consumer Product Safety Authority (nVWA) considers a proper risk assessment pivotal as basis for a legal underpinning of the statement in Regulation (EC) 767/2009 (see Annex 1).
In the assumption that FFPs are intended for feeding to animals instead of directing them to other purposes (see Figure 1), several ethical considerations apply. On one hand major amounts of edible products should remain available for consumption of any sort. The use of FFPs for feeding opens the possibility that other even more valued and qualified products can be used for human consumption instead of for feeding purposes. On the other hand, animals should be prevented from eating all kinds of contaminants, including remnants of packaging materials. The compromise between these two considerations is only acceptable when a sufficiently low level of risk can be achieved. It should be noted that a society without risks does not exist. Therefore, “a sufficiently low level of risk” is definitively higher than zero risk, and any “accepted” level of risk should be compared with other comparable products and situations. Such a comparison and a discussion on the acceptability is a task of society. This report will merely provide some of the basic data which can drive this discussion.

3.2 Types and application of products

3.2.1 Bakery products

This category includes dried and ground meal from bread and biscuit products. Biscuit meal comprises biscuits, treacle waffles, chocolate (not confectionary), gingerbread, breakfast cereals, crisps, nuts, a.o. The estimated volume of recycling in the Netherlands is approx. 150,000 MT. Approximately an identical volume is imported from surrounding countries, especially Germany, which means that approx. 300,000 MT of bakery products are processed to yield animal feed.
The processed bread is predominantly packaged, while the majority of the biscuit products is processed unpacked (ca. 80 %).

3.2.2 Other dry products

Dry products further include sweets and dairy powders. As far as these FFPs are recycled as ingredient in animal feeds, the annual volume is approx. 40,000 MT.
Sweets, originally dry products, are processed in the form of syrup by dissolving and removing packaging materials from the wet product (see chapter 3.4).

3.2.3 Other wet or moist products

Most wet products are being used for fermentation. In a few cases (e.g. dairy products, beverages) a part of the total volume of FFPs is being used for feeding. The share of this type of product intended as ingredient in animal feeds is 30,000 MT annually at the most. Assuming a dry matter weight of 12%, the annual volume dry matter does not exceed 4,000 MT.

3.2.4 Targeted animals

Bakery products and chocolate products are well suited for feeding pig, due to the high amount of digestible carbohydrates and their palatability. Moist or wet FFPs are useful for so-called wet-feed processors and are also intended for pigs.
Dry dairy products are normally used as feed ingredient of young animals, e.g. piglets and calves.
Sugar-rich materials (candy syrups) are being used as replacement of molasses, which is used as a binding agent during the pelleting of feed. This application is useful for pelleted feed for all kind of animals.

3.3 Types of packaging materials

Materials used for food packaging are very diverse. Each food requires a packaging material that protects the food from the environment and that is capable to assure a shelf-life as long as possible. For food products relevant for reclaiming and re-use in feed production, mainly plastics and paper and board packaging materials are used. Packaging may be sub-divided into polyolefins (PO, including polypropylene (PP) and polyethylene (PE); [4]), polyethylene terephthalate and its copolymers (PET; [5]), polystyrene (PS; [6]), rigid polyvinylchloride (PVC; [7]), regenerated cellulose (RC; [8]), paper and board [9] and aluminium [1] foil [10]. Any combination of these materials may appear in daily life. In addition the packaging materials may be manufactured using adhesives and they may be printed on the outside.

3.3.1 Basic principles for food contact materials

The packaging materials used with the FFP cover a large range of materials with often very complex compositions (Barlow, 2009). The materials used for the packaging of human foods have to comply with specific regulations. The European Regulation (EC) 1935/2004 (European Commission, 2004) covers the general requirements for all types of packaging materials. It requires that packaging materials shall not release their constituents at a level that could endanger human health. Specific EU directives have been published which regulate in great detail the composition of plastics (European Commission, 2002) and regenerated cellulose (European Commission, 2007). Other packaging materials (e.g. paper, board, coatings or aluminium foil) are regulated in detail at national level. The German BfR has published recommendations for various materials [11]. Of these, the Recommendation XXXVI (BfR, 2009) concerning paper and board may be considered the most relevant. In The Netherlands, the "Packaging and food utensils regulation" (WVG, 2010) sets requirements to a broad variety of materials intended to come into contact with food (FCM), among which packaging materials. The chapters on paper and board and on coatings as included in the Dutch regulation are of particular relevance for the risk evaluation of FFP in feeds.
The evaluation of FCM (read in the current context: packaging materials) is directed at chemicals to be included in the production process of these materials and to the migration of these chemicals from the packaging materials into the foods (Munro et al., 2002; Lee, 2010). The final FCM as such (e.g. the plastic film) are actually not evaluated. However, any FCM should comply with the general requirements as laid down in Regulation (EC) 1935/2004.

---

[1] British English spelling is used throughout the manuscript, according to Collins Advanced Dictionary (2009).

Chemicals authorized to be used in the production of FCM are evaluated for their toxicological properties. In the toxicological evaluation a tiered approach is applied (Barlow, 2009). The set of required toxicological data is related to the actual migration. If migration is <0.05 mg/kg food then only absence of genotoxicity needs to be demonstrated, for which at least three *in vitro* mutagenicity tests are required. If migration is >0.05 mg/kg food but <5 mg/kg food, then additionally a 90 days feeding study and demonstration of the absence of accumulation in man shall be provided. If migration is >5 mg/kg food then a long term feeding study, reproduction study and data on absorption, distribution, metabolism and excretion are needed.

Based on the available set of toxicological data and the toxicity profile the release of a substance is restricted. Restriction may include a specific migration limit (SML) expressed in mg/kg food, a maximum quantity in 6 dm^2 [2] of material (QMA) or a maximum quantity in the material expressed in mg/kg polymer (QM).

The risk evaluation for chemicals migrating from FCM starts from the assumption that a person, with a body weight of 60 kg, eats live-long every day one kg of food packaged in a material that contains the relevant substance, while that kg food is in contact with 6 dm^2 of packaging material. The maximum accepted level of migration is 60 mg/kg food but lower levels are often established. In practice, SMLs may vary from 0.01 mg/kg up to 60 mg/kg food. For many substances, SMLs have been set at 0.05 or 5 mg/kg. These values are the same cut-offs which govern the tiered approach for toxicological data requirements (Barlow, 2009).

The SML may be considered to reflect the possible maximum daily exposure of a person. It is emphasized that the two default SMLs of 0.05 mg/kg food and 5 mg/kg food, respectively, do not represent the actual toxicity, but rather indicate that these SMLs have been derived with a very limited package of toxicity data. However, for the substances for which the SMLs are either of these two values, no appreciable toxicological risk is anticipated, provided that their migration into foods remains below their respective SMLs. For substances for which the SML deviates from these values, a direct link between the toxic potency of those substances and the SML can be identified.

The mentioned assumptions and considerations indicate that focus is primarily on the effect of migration from FCM to food for human consumption (Munor et al., 2002; Lee, 2010). In the risk evaluation of the use of FFPs in *feeds*, other data or considerations on the FCM may be relevant (e.g. data on transfer to meat or milk or information on exposure to a specified food and packaging). Ultimately these additional data or considerations could lead to migration restrictions for animal feed which could deviate from the restrictions considered suitable to control human exposure.

In further consideration on risk of the feeds containing FFP-packaging materials, it is taken that residual packaging material in the feeds has been submitted to the usual processing of FFPs. This results in small particles of packaging materials with a maximum size of approximately 1 cm^2 in the feed. It is assumed that the residual packaging materials shall not exceed a level of 0.15% w/w in the processed FFP. Mixing 10% FFP in a final feed would then result in a level of 0.015% w/w of packaging material in the final feed (or 150 mg/kg feed). This conservative estimate of the maximum level of contamination will be considered in further risk evaluations in this report.

For none of the substances considered below, health-based criteria for animals are available. Therefore, the risk evaluation for these chemicals for animals will be assessed, based on the migration criteria applicable for human consumption, assuming that food that is safe for humans, will also be safe for animals. In addition, for the evaluation, the carry-over from animal feed to food for humans (i.e. milk, meat, eggs) should also be taken into account.

---

[2] A standard assumption in FCM evaluations is that 1 kg of food is packed into 6 dm^2 (a box with a content of 1 L)

3.3.2 Plastics

Plastics are built by polymerisation of monomers. Residual monomers may be present in the plastic but they are almost by definition very low and in compliance with EU requirements. Additives, substances added to the polymer to achieve a physical or chemical effect in the plastic, may be added in various amounts depending on the function but also on the polymer type itself. For instance, antioxidants are added in levels of 0.1 - 0.5%, fillers at 1-50%, polymeric additives at 0.5 – 10%, light stabilizers at ±0.3%, optical brighteners at 0.025%, antistatics at ± 0.1%. To many additives SMLs have been allocated. It should be taken into account that migration depends on the properties of the substance (Molecular weight, polarity, lipophilicity, solubility in water or fat), the diffusion properties of the plastic (LDPE [12] is high diffusive and PET, PVC, PS are low diffusive materials), the concentration of the substance in the plastic, the food type (aqueous or fatty) and the contact conditions of the food with the packaging material (time and temperature conditions).

3.3.3 Paper and Board

Paper and board is the second most frequently used packaging material after plastics. Paper and board is widely used in direct contact with dry foodstuffs. For contact with wet or fatty foods the paper and board needs to be treated with substances that make the paper and board suitable for the intended purpose. Paper and board are composed of fibres obtained from different sources, including recycled materials. In paper making quite a lot of chemicals are needed to make the final product. It should be borne in mind that many of the chemicals used in paper making are used on the wet end and often the bulk of chemicals are removed together with the process water. For instance, biocides are added to process water to prevent growth of slime-producing organisms, but such biocides are not retained in the paper.

3.3.4 Regenerated cellulose (RC)

Coated or uncoated regenerated cellulose is frequently used for packaging of some types of bakery products. However, in the view of the total diversity of packaging materials, the share of RC is low. The composition of regenerated cellulose is subject to EU-harmonised legislation (Regulation (EC) 2007/42; European Commission, 2007). In the practice of removing the remnants of packaging materials and of the monitoring of the results of the cleaning procedure (see chapter 3.5) regenerated cellulose is treated as part of the major category “plastic”. However, it should be realised that its chemical composition is quite different from that of other food contact materials.

3.3.5 Aluminium foil

Aluminium is used as trays for packaging of some types of bread and, in the form of thin foils, as wrapping of candy bars. Additionally, aluminium coated paper is frequently used to pack chocolate bars and some sweets. Even after processing and cleaning, this type of coated paper can be identified as such in the re-processed FFP and is therefore an item in de inventory of the Dutch monitoring program (see 3.5).

3.3.6 Ferro-metals

Although with a minor share, metal wires and closing clips are being used as packaging materials for several food products. Direct contact with food does not exist, and as a consequence European legislation for FCM does not apply. Ferro-metals can be extracted from FFPs when applying magnets (see Annex 4) which makes this type of material distinguishable from aluminium foil and other packaging materials. Moreover, ferro-metals can be recognised in monitoring of samples of FFPs (see chapter 3.5).

3.3.7 Printing inks

Many food packaging materials are printed on the outside (i.e. the non-food contact side) of the packaging material. Because there is no direct contact with the food, the European Union and the member states have not drafted legislation on printing inks. This makes a risk evaluation cumbersome. Printing inks are very complex mixtures. They basically exist of pigments or colorants and a so-called carrier. In addition it should be taken into account that printing is applied in thin layers (maximum 10 μm) and often not covering the total surface area.
France has regulated some specific colorants. Germany and The Netherlands have regulated pigments and colorants and they have set solubility limits for pigment metals and a restriction for the presence and migration of primary aromatic amines.
Printing inks do not show up as a separate fraction in the remnants of packaging materials, if any, but they are inseparable parts of other packaging materials such as plastics, paper/board and thin aluminium foils. From a toxicological point of view a separate discussion of printing inks is worthwhile, but in the practice of monitoring printing inks do not form a separate category (see chapter 3.5).

3.4 Unpacking processes

The application of unpacking processes depends on the nature of the product. Annex 4 provides an overview of the relevant procedures and techniques. Besides manual unpacking of specific products (section C in Annex 4), procedures are automatic (line processing) in order to be able to handle larger quantities in a (semi-)continuous line. Principally several subsequent actions have to be carried out to get a final product ready for further use as animal feed ingredient. These steps are:

1. Treatment of FFP to make the material ready for separation. The packaging has to be opened or broken, and reduced in size or cut down in order to get access to the FFP for further processing such as drying or dissolving.
2. Processing of FFP to a ready product.
3. Final removal of remains of packaging materials. Several procedures depend on specific characteristics of included packaging materials such as fragment size (sieving), density (plastic), magnetic attraction (ferro metals), Eddy current separation (non-ferro metals, [13]), etc.

Figure 3 provides an overview of procedures for three examples of FFPs. Further details for the mentioned procedures are given in Annex 4.

<table>
<tr><th>Bakery products</th><th>Sweets</th><th colspan="2">Wet dairy products</th></tr>
<tr><td>A1. Coarse grinding</td><td>B1. Coarse grinding</td><td>C1a. Crushing or rolling</td><td>C1b. Squeezing</td></tr>
<tr><td>A2. ➩ Removing of the major part of packaging material by wind sifting and sieving</td><td>B2. Dissolving in water</td><td>C2a. ➩ Sieving</td><td>C2b. ➩ Sieving</td></tr>
<tr><td>A3. Drying (if necessary)</td><td rowspan="2">B3. ➩ Sieving</td><td rowspan="2">C3a. ➩ Further sieving or centrifugation if necessary (e.g. glass)</td><td rowspan="2"></td></tr>
<tr><td>A4. ➩ Removal of remains of packaging material:
• Plastic and paper: wind sifting
• Ferrous metals: magnet
• Non-ferrous metals: Eddy current separation</td></tr>
</table>

Figure 3. Order of procedure for unpacking of several FFPs. Difference is made between treatment processes and separation processes (latter indicated by ➩).

The impact and the final effect of the different processes differ, although in most cases optimisation has been reached to a large extent (see also Kamphues, 2005). Comments can be made to some examples listed in Figure 3.

- A4. Removal of plastic and paper remains depends on the density and size of packaging snippets. Well controlled air flows can remove most particles from the FFP. Cuttings of plastic closing clips, however, are heavier and are more difficult to remove with this technique.
- B3. Pieces of aluminium foil or plastic wrappings of sweets and candies can easily be removed from sweet syrups after grinding and dissolving. If occasionally paper or board is part of the packaging materials, the fibres are difficult to remove since these may dissolve as well in the fluid. Specific treatment of these materials during monitoring will reveal the presence of fibres (see chapter 3.5).
- C1 and C2. Grinding of flexible laminated paper or board packs (e.g. Tetra Pak ® for dairy products) will results in fibres which are difficult to remove from the wet product. Alternatively, only squeezing of those packs will also result in the release of the FFP, resulting in large sized remains, which can be removed easily. Wet products which are packed in cans or bottles can not be treated otherwise than crushing or grinding. However, from these packaging materials only high-density fragments will arise, which can in principle be removed by sedimentation / centrifugation.

3.5 Monitoring of packaging materials in samples from practice

From 2005 on, the Dutch nVWA had the analysis of remains of packaging materials in FFPs that are intended to be used as feed material conducted. The majority of these samples (160 out of 243) consists of dried and ground bakery products (bread and biscuit meal). Some other categories are sweets (in the form of syrups), chocolate products, and dairy products (predominantly milk and whey powders). A remainder category consists of a diversity of products, ranging from vegetable products, potato products, dough for baking, to starch products. An overview of the types and numbers of samples are presented in Table 1. The category "other" show a high number of investigated samples in 2007, due to a special project subjected to these products for that year. Nevertheless, in all cases the results were obtained after random selection of samples. Targeted sampling has been excluded from these results.

Table 1. Number of samples per year and category in the Dutch monitoring program of FFPs.

category	total	2005	2006	2007	2008	2009	2010
bakery products	160	25	39	19	21	24	32
sweets	17	5	5	1	3	1	2
cocoa	27	2	11	3	1	4	6
dairy	10		1	3	1	1	4
other	29	3	4	16	2	3	1
total	243	35	60	42	28	33	45

The samples were collected by the nVWA and submitted to RIKILT for analysis. The analysing method can briefly be summarised as: 1) visual selection of undesired ingredients which can be identified as remnants of packaging materials, 2) weighing of the selected materials, 3) defatting, 4) dehydration, 5) final weighing, 6) reporting of weight and percentage. In all cases the total amount of the sample material was investigated, which is usually 500 grams. This procedure prevents inhomogeneity of the sample to be a problem. The method has been validated at RIKILT for bakery products, including sweet bread and raisin bread, with a detection limit of 0.01% w/w and a recovery between 93% and 102% (RIKILT, unpublished results).
The report of every sample mentions the finding of residual materials or ingredients of unknown source, that are uncommon or foreign for that sample, in short referred to as “foreign material”. The relationship between any foreign materials found and packaging materials is legally complicated (see also Annex 3).
Remains of presumed packaging materials are not automatically identical to their original appearance. An overview of the appearance of recovered materials is given in Figures 4-7. Paper, board and carton can be modified and can show up as fibres in general, especially in wet products (see Figure 7). Plastics of different kinds (including regenerated cellulose; see previous paragraphs) are identified in general as “plastic”. Aluminium foil or aluminium coated paper is usually recognisable as such and reported as a separate type (Figure 6). When a certain modification of the visual appearance applies, the final form is reported.
The frequencies of the presence of four different types of foreign materials in five different categories of FFPs are reported in Table 2.

Fibres originating from paper and board show the highest abundance in the investigated samples. Plastics are second in frequency of occurrence. The number of samples analysed in the category of dry dairy products (see Table 1) is not sufficient to draw any conclusions from the frequencies of occurrence as presented in Table 2. The category “other” show a diverse view among the years. Foreign materials are found in 2007 with a low occurrence. Nevertheless, the samples investigated in that year for the category “Other” are not principally different from those of the other years.

Table 2. Number of positive samples (#) and percentage of positive samples (%) for packaging materials with an indication of type of material and of year in the Dutch monitoring program of FFPs.

category	positives: material	2005 #	%	2006 #	%	2007 #	%	2008 #	%	2009 #	%	2010 #	%
bakery products	fibres	25	100%	30	77%	12	63%	15	71%	23	96%	22	69%
	plastic	13	52%	26	67%	12	63%	14	67%	23	96%	26	81%
	alu *	5	20%	5	13%	6	32%	5	24%	9	38%	11	35%
	metal		0%	1	3%	1	5%		0%		0%		0%
sweets	fibres	5	100%	5	100%	1	100%	3	100%	1	100%		0%
	plastic	1	20%	4	80%		0%		0%		0%	2	100%
	alu	2	40%	5	100%	1	100%	2	67%	1	100%	1	50%
	metal		0%		0%		0%		0%		0%		0%
cocoa	fibres	2	100%	10	91%	1	33%	1	100%	3	75%	4	67%
	plastic	1	50%	9	82%		0%	1	100%	2	50%	4	67%
	alu	2	100%	7	64%		0%	1	100%	3	75%	2	33%
	metal		0%		0%		0%		0%		0%		0%
dairy	fibres				0%		0%	1	100%		0%		0%
	plastic				0%		0%	1	100%		0%		0%
	alu				0%		0%	1	100%	1	100%		0%
	metal				0%		0%		0%		0%		0%
other	fibres	3	100%	2	50%		0%		0%		0%	1	100%
	plastic	2	67%	3	75%		0%	1	50%	1	33%	1	100%
	alu		0%		0%		0%	1	50%	1	33%	1	100%
	metal		0%		0%		0%		0%		0%		0%

** "alu" indicates aluminium foil as well aluminium coated paper that is usually used as wrapping of sweets a.o..*

The presentation of Table 2 shows the *frequencies* in which the several types of foreign materials occur in the samples only. However, the *levels* at which these foreign materials were found indicate the severity of the presence. The average levels for the different categories of FFPs are shown in Table 3. Since the target of all investigations was the establishment of the presence "foreign materials" in general, no stratification is available per type of foreign material.

Table 3. Average levels of packaging materials (in % w/w) with the standard deviation in brackets (SD) in samples of different categories for different years in the Dutch monitoring program of FFPs.

category	2005 mean (SD)	2006 mean (SD)	2007 mean (SD)	2008 mean (SD)	2009 mean (SD)	2010 mean (SD)
bakery products	0.04% (0.04)	0.04% (0.04)	0.04% (0.06)	0.03% (0.03)	0.04% (0.05)	0.06% (0.14)
sweet	0.42% (0.29)	0.20% (0.08)	0.44% (-)	0.02% (0.02)	0.01% (-)	0.01% (0.00)
cocoa	0.04% (0.02)	0.13% (0.00)	0.00% (0.01)	0.09% (-)	0.05% (0.03)	0.05% (0.07)
dairy		0.00% (-)	0.00% (0.00)	0.01% (-)	0.01% (-)	0.00% (0.00)
other	0.02% (0.01)	0.03% (0.04)	0.00% (0.00)	0.34% (0.48)	0.01% (0.02)	0.01% (-)

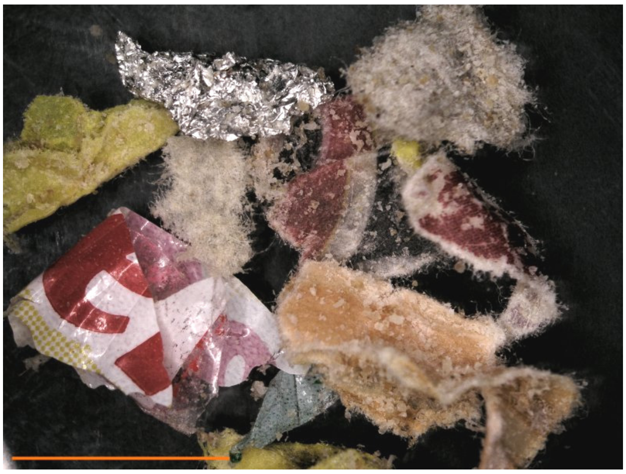

Figure 4 and 5. Presumed remnants of packaging materials in bakery products. Bar in lower left corner is 1 cm. Figure 4 (left): mixture with aluminium particles, paper and printed foil; complete overview of the recovered material from a sample with a contamination level of 0.21 % w/w. Figure 5 (right): pieces of plastic clips among other particles; complete overview of the recovered material from a sample with a contamination level of 0.05 % w/w.

Figure 6 and 7. Presumed remnants of packaging materials in a cocoa products and in a sweet syrup. Bar in lower left corner is 1 cm. Figure 6 (left): aluminium foil and plastic; complete overview of the recovered material from a sample with a contamination level of 0.2 % w/w. Figure 7 (right): conglomerates of paper fibres collected from a sweet syrup; part of the recovered material from a sample with a contamination level of 0.44 % w/w.

With only a few exceptions, the average levels of foreign materials found are low. An examples of the full amount of recovered material at the average level of 0.05% w/w in bakery products is shown in Figure 5. A notable situation occurs in the category of syrups of sweets. Up to 2007, considerable levels were found, while from 2008 these levels are principally lower, and actually lower than found in several other categories of products in the same years. Only in a few other cases, i.e. cocoa products in 2006 and other products in 2008, it is helpful to go in further detail. Such a more detailed presentation can be achieved by considering the individual samples with relatively high levels of foreign materials. The levels are considered “high” only in a relative way, since no level higher than 0.71% w/w was found. In order to illustrate the effect of a tolerance limit of 0.15% w/w in the framework of a “what-if” analysis, a view of the number of samples with higher levels, and the maximum amount found is presented in Table 4.

Table 4. Number of samples (#) with a percentage of packaging materials over 0.15% w/w and the maximum level found in samples of different categories for different years in the Dutch monitoring program of FFPs.

	2005		2006		2007		2008		2009		2010	
category	#	max level	#	max level	#	max level	#	max level	#	max level	#	max level
bakery products	1	0.21%	1	0.19%	1	0.22%	0	0.10%	0	0.23%	2	0.71%
sweet	4	0.70%	4	0.30%	1	0.44%	0	0.04%	0	0.01%	0	0.01%
cocoa	0	0.05%	2	0.36%	0	0.01%	0	0.09%	0	0.08%	1	0.17%
dairy			0	0.00%	0	0.00%	0	0.01%	0	0.01%	0	0%
other	0	0.03%	0	0.08%	0	0.00%	1	0.68%	1	0.03%	1	0.01%

Notable individual samples were:

- A: Bakery product, 2010 (0.71% w/w): bread meal containing fibres, aluminium laminated paper, plastic.
- B: Bakery product, 2010 (0.41% w/w): Bakery product with predominantly fibres, aluminium laminated paper, plastic.
- C: Sweet syrup, 2005 (0.7% w/w): syrup without further indication, with fibres, aluminium laminated paper.
- D: Sweet syrup, 2005 (0.7% w/w): syrup without further indication, with disorganised fibres, sand particles.
- E: Sweet syrup, 2005 (0.4% w/w): syrup without further indication, with fibres, aluminium laminated paper.
- F: Sweet syrup, 2007 (0.44% w/w): syrup without further indication, with fibres glued together in conglomerates, few aluminium laminated paper: Figure 7.
- G: Cocoa product, 2006 (0.36% w/w): powdered product without further indication, with fibres, aluminium laminated paper, several types of plastic.
- H: Other product, 2008 (0.68% w/w): mixed product containing aluminium laminated paper, plastic.

A “What if” analysis of the results of the Dutch monitoring program with respect to several putative tolerance levels showed that any level between 0.1 % w/w and 0.2 % w/w does not cause major differences in the number of samples to be rejected (Table 5). The share of samples higher than a fixed tolerance level ranged from 6.6 % (tolerance level 0.2 % w/w) to 9.9 % (tolerance level 0.1 % w/w). The majority of samples (> 90 %) showed acceptable low levels of remnants of foreign materials, and only a small number of samples showed notable amounts of foreign materials. Approx. 60 % of the non-compliant samples belonged to the categories sweet and cocoa products. For the major category in the study, bakery products, 5 % or less of the samples exceeded the tolerance level, depending on the threshold level.

Table 5. Effect of fixing several tolerance levels (0.1% w/w, 0.15% w/w and 0.2% w/w) on the number of non-compliant samples resulting from the Dutch monitoring program 2005-2010.

category	total # samples	# (%) samples > 0.1 % w/w	# (%) samples > 0.15 % w/w	# (%) samples > 0.2 % w/w
bakery products	160	8 (5.0 %)	7 (4.4 %)	5 (3.1 %)
sweet	17	9 (52.9 %)	9 (52.9 %)	7 (41.2 %)
cocoa	27	6 (22.2 %)	5 (18.5 %)	3 (11.1 %)
dairy	10	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
other	29	1 (3.4 %)	1 (3.4 %)	1 (3.4 %)
Total	243	24 (9.9 %)	22 (9.1 %)	16 (6.6 %)

3.6 Risk inventory animals

To make a risk evaluation, it is necessary to assume a maximum amount at which a substance might be present in the feed. As indicated above (see chapter 3.3.1) a maximum level of 0.015% w/w of packaging material in feed will be assumed for the current evaluations (i.e. 150 mg/kg feed, based on a share in feed of 10 % of FFP, containing 0.15 % (w/w) packaging materials).

3.6.1 Chemical risks

3.6.1.1 Plastics

Since additives in a general sense are only a fraction of the matrix of FCMs, such substances might be present in the feed at levels that are less (often much less) than the mentioned 150 mg/kg. Any substance for which no SML has been established is allowed in food up to the maximum overall migration limit of 60 mg/kg food (see chapter 3.3.1). Therefore, substances without an established SML, which are present in the plastic in a concentration of less than 40% (as 60 mg/kg is 40% of 150 mg/kg) are not expected to cause a health risk.

Fillers: only fillers may exceed a level of 40% of the total matrix of the food contact material. Fillers are inorganic substances like calcium carbonate, titanium dioxide, glass fibres or clay. These substances have very low toxic potency, or they will not migrate from the plastic or they are not soluble in body fluids resulting in poor absorption. Consequently for these fillers a health risk to livestock is not anticipated.

Monomers: Some of the monomers have been assigned with a SML of “Not Detectable” (ND). Some monomers have a QM of 1 mg/kg of plastic (see Directive 2002/72/EC [3]). Actually this group of substances is of real concern as they are reactive and some of them have been found to be genotoxic.

In the Directive 2002/72/EC, ND means a migration less than a specified detection limit of 10 µg/kg food. In the FCM evaluation and authorisation process, it is conventionally assumed that migration occurs from a layer with a maximum thickness of 0.25 mm. If it is assumed that the density of the material is 1 g/cm^3, then the weight of 6 dm² is 15 g. If all residual monomer migrates (e.g. from a

[3] This Directive will remain in force until May 1st, 2011, after which it will be replaced by Commission Regulation 10/2011/EC. This change in legislation will not affect the evaluation described in this report.

polyethylene film), then for a monomeric substance with a migration limit of 10 µg/kg food, the residual content of the monomer in the plastic is equal to 10 µg/15 g polymer. The feed contains only 0.15 g of plastic/kg and thus the maximum amount of that monomer is only 0.1 µg/kg feed. From such low concentrations, a health risk is not anticipated, irrespective of the chemical nature of the monomeric substance. If the monomer is present in a low diffusive material (e.g. PET, PS, PVC), then the migration to food might be only 1% of the actual amount present and subsequently exposure and associated health risk will be even lower.

Because the residual plastic in the FFP has been processed to small particles the leaching of the monomer from the plastic particles, even from a low diffusion polymer, may be significantly higher under GI-tract conditions. In such a case the exposure may increase up to 10 µg/kg feed as a worst case (assuming 100% migration within the GI-tract), but even then the migration is only up to a barely detectable level.
As mentioned above, for some monomers also a QM of 1 mg/kg plastic has been established. Assuming 100% migration, this will result in a concentration in feed of 0.15 g plastic/kg feed × 1 µg monomer/g plastic = 0.15 µg monomer/kg feed, which is at any rate far below the SML of "ND".

Additives: Additives, a group of substances with a wide variety of chemical and physical properties, may be used in plastics manufacturing. It is not feasible to discuss every additive. Therefore some typical examples authorised in Directive 2002/72/EC with low and high SMLs will be discussed.

- 2-Aminobenzamide (Ref No 34895) is used as an acetaldehyde scavenger in PET at a maximum concentration of 500 mg/kg plastic. The SML = 0.05 mg/kg food. The substance is soluble in water. The actual amount present in the feed may be as high as 500 (mg/kg polymer) × 0.15 g polymer/kg feed = 75 µg/kg feed. This would exceed the SML of 0.05 mg/kg food. However, PET is a low diffusive material and using a calculation model for diffusion (Directive 2002/72/EC; e.g. Fick's equation, [14]) it is obvious that only a minor amount of the substance will be released during the retention time in the GI-tract of animals.
- 4,4'-Bis(2-Benzoxazolyl)stilbene, (Ref No 38515) is used as an optical brightener in all types of plastics at a maximum concentration of 250 mg/kg polymer. The substance is water insoluble. The SML = 0.05 mg/kg food. The actual amount present in the feed is 250 (mg/kg polymer) × 0.15 g polymer/kg feed = 37.5 µg/kg feed. Assuming 100% migration, the concentration of the substance in the feed would not exceed the SML of 0.05 mg/kg food.
- Alkyl(C12-C20)dimethylamine (Ref No 34130) is used as an antistatic and wetting agent in all plastic types at a maximum concentration of 100 mg/kg polymer. The substance is slightly soluble in water. The SML = 30 mg/kg. The actual amount present in the feed is 100 mg/kg polymer × 0.15 g polymer/kg feed = 15 µg/kg feed. The SML value cannot be exceeded in this case.
- 1,1,3-tris(2-methyl-4-hydroxy-5-tert-butylphenyl)butane (Ref No 95600) is used as an antioxidant in all types of plastics at a maximum concentration of 2000 mg/kg in PE. The substance is poorly soluble in water and an SML = 5 mg/kg food has been set. The actual amount present in feed is 2000 mg/kg polymer × 0.15 g polymer/kg feed = 0.3 mg/kg feed. The SML value cannot be exceeded in this case.
- 6-Amino-1,3-dimethyluracil (Ref No 35160) is used as a heat stabilizer in PVC at a maximum concentration of 0.5%. The SML = 5 mg/kg. The substance is moderate soluble in water. The actual amount present in the feed is 0.5% x 0.15 g polymer = 0.75 mg/kg feed. The SML value can not be exceeded in this case.

- Antimony trioxide (Ref No 35760) is used as a flame retardant in PET at a maximum concentration of 350 mg/kg polymer. The SML = 0.04 mg/kg. The substance may be soluble in acidic conditions. The actual amount present in the feed is 350 mg/kg polymer × 0.15 g polymer/ kg feed = 53 μg/kg feed. Theoretically the SML can be slightly exceeded, but in this case the polymer is a low diffusion material and 100% leaching is very unlikely. Migration experiments with 3 % acetic acid for 10 days at 40ºC have demonstrated a very low migration.
- Colorants are frequently added to plastics but no harmonised EU legislation has been developed. The colorant may be organic or inorganic and they are subject to national legislation. Both the Dutch regulation and the BfR have formulated purity requirements with respect to the solubility of the pigment in 0.1N hydrochloric acid. In addition migration limits for some metals and for primary aromatic amines have been established. It is considered that the remnants packaging materials in feed are in compliance with the relevant packaging regulations. Taking into account the low residual content it is considered that the release of metals or primary aromatic amines will be low or not detectable.

From these examples, it may be concluded that only additives which are used in relatively high concentrations, in high diffusive plastics (assuming 100% migration) and with low SMLs might exceed the SML value. However, since it can be anticipated that under such conditions, the additive cannot be safely used in FCM intended for contact with human foods, it is very unlikely that such combinations would be present in feed as a result of feed contamination with FCM from FFP. As a conclusion, in the presented examples of additives the discussed SMLs will not be exceeded and risks are not identified

3.6.1.2 Paper and board

For a risk evaluation only substances that are intended to remain in the paper are relevant. Unlike plastics, paper particles will disintegrate in the GI- tract (see Kamphues, 2005) and thus all substances present in the paper will become available. Major groups of paper additives are discussed below.

Fillers: Beside fibres, paper contains significant amounts of fillers. The fillers are salts of carbonates, silicates and sulphates. They are insoluble or non-toxic to humans and no risk is identified for the same reasons as given for the anorganic fillers in plastics (see above).

Sizing agents: Sizing agents are added during paper making to make the paper more hydrophobic and to influence dewatering. Colofonium, starch derivatives and various copolymers are the major substances used. The BfR recommendation XXXVI has set maximum use levels for most of the sizing agents ranging from approximately 0.1 – 4 %, but a level of 0.5 – 1 % is frequently used. In addition purity requirement are formulated. Isocyanate- or acrylamide-based copolymers should not contain detectable amounts of primary aromatic amines or acrylamide in an aqueous extract of the paper. This kind of purity requirements prevent the presence of these unwanted substances in FCM that shall comply with the relevant rules. The copolymers may or may not be soluble in water but even if they are soluble in water their molecular weight will be much higher than 1000 Da and therefore in general these copolymers will show a very limited availability for absorption after digestion of the paper material (cf. Fix, 1996). For sizing agents, a risk is not identified.

Retention agents: Retention agents are added in order to maintain functional chemicals in the paper. Polyacrylamides, polyethylene-imines and polyamides and their copolymers are used at levels of 0.5 –

0.1%. These polymers should comply with requirements on residual levels of toxic monomers like e.g. epichlorohydrine, acrylamide, ethyleneimine and 1,3-dichloro-2-propanol and should not be detectable in an aqueous extract of the paper. As it concerns FFP, the paper shall comply with these restrictions and therefore no risk is identified, taking into account the low level of anticipated contamination of feeds (<0.015% w/w) with paper.

Biocides: Slimicides are used in the process water and are not intended to be present in the final paper. Paper preservatives are added to the paper to avoid mould or bacteria growth on the paper. The BfR Recommendation XXXVI has set maximum use levels and a requirement that the final product should not exhibit any inhibition in bacterial growth in a special test. For instance, in a paper the presence of a mixture of 5-chloro-2-methyl-4-isothiazoline-3-one (approx. 3 parts) and 2-methyl-4-isothiazoline-3-one (approx. 1 part) should not exceed 0.5 µg/dm². Assuming a paper weight of 100 g/m² this would be equivalent to 0.5 µg/g paper. If the feed would be contaminated with 0.15 g of paper/kg feed then the maximum amount of the preservatives would be 0.15 x 0.5 µg = 0.08 µg/kg feed and it may be concluded that a risk is not identified. A similar calculation may be made for other preservatives but as they are authorized to be present at a higher level, the outcome will be the same.

Surface refining and coating agents: Surface refining and coating agents are often used to improve the water and/or fat resistance of the paper. Applying a surface coating allows contact with fatty foods or aqueous foods. The agents are applied to the food contact side of the paper. However also on the outside coatings may be applied to improve the printability of the paper.

- Polymers of the same composition as plastics may be applied. For such polymeric coatings, risk considerations similar to those made for plastics above would apply. Taking into account that coatings are much thinner than plastic films, no risk is identified.
- Often mineral hydrocarbons like paraffin wax are used. The paraffin should comply with purity criteria. No SML is defined for the release of paraffin, but for such high molecular weight mineral hydrocarbons extensive toxicological evaluations are present, indicating very low oral toxicity (e.g. JECFA, 2002). Migration exceeding 60 mg/kg is very unlikely.
- Chromium complexes with fatty acids may be applied up to 0.4 mg chromium III/dm² based on chromium. Extraction to cold water should not exceed 0.004 mg chromium III/dm². However upon digestion all applied chromium may become available for absorption due to the low pH of the gastric fluid. The worst case exposure from chromium-treated paper might be 0.4 mg x 0.15g = 0.06 mg/kg feed. This value exceeds the extraction level by a factor of 15. However in the Netherlands a migration limit of 0.1 mg/kg food has been established. In addition the Council of Europe recently published a draft document on metals in which they propose a specific release limit (SRL) of 1 mg/kg food. The calculated worst case exposure to chromium is significantly below the migration limit or SRL set by the Netherlands and the Council of Europe, respectively. In addition, also the European Scientific Committee on Food has indicated that in humans supplementary intake of chromium (III) up to 1 mg/person/day (equivalent to 1 mg/kg food) is not associated with adverse effects (European Commission, 2003). Therefore, up to the anticipated level of release from paper and board in feed, no risk is indicated.
- Modern sizing agents [4] are copolymers of perfluorinated acrylates and methacrylates with some other monomers. These copolymers are poorly soluble in aqueous media and in addition their molecular weights are for a major part higher than 1000 Da and therefore these copolymers are

[4] Sizing agents in this respect are part of surface and coating materials instead of being part of the paper itself.

only poorly absorbed. Taking into account the low amount of paper in the feed and the properties of the perfluoro-compounds (poor solubility and high Mw), a health concern is not identified. In addition, it is noted that the use of perfluoro-octanoic acid, which is environmentally persistent, bioaccumulative and suspected to be carcinogenic in animals, has been faded out and has therefore not been considered in this evaluation.

3.6.1.3 Regenerated cellulose

Softeners: Regenerated cellulose (RC) contains various polyols at a maximum of 27% as softeners or "moisture regulators". Polyols like glycerol are of no concern with respect to risk for humans. However, ethylene glycol (EG) and diethylene glycol (DEG) may result in a worst-case concentration of 41 mg/kg feed (270000 mg/kg $\times$ 0.15 g/kg) while the migration limit for human is set at 30 mg/kg. In principle this could indicate a health concern. In view of a generally limited presence of RC in FFPs (see chapter 3.3.4), it must be anticipated that the feed will be contaminated with EG- and DEG-containing RC only rarely and thus in general, the levels of these two substances in feed will be less than the SML of 30 mg/kg. Therefore, a risk is also not identified for these two substances, if released from regenerated cellulose containing EG or DEG up to the maximum level allowed.

Other additives: Additives other than softeners are allowed but at very low amounts. It mainly concerns polar substances which certainly will be released during passage through the GI-tract. However, considering the magnitude of the levels allowed and considering the chemical nature of these substances (see Regulation (EC) 2007/42), a risk is not identified.

Coatings: Coatings applied on the food contact side are allowed. Mainly polymers and resins are authorised. Their composition and the maximum quantity to be applied are regulated. Additives used in the coating are also listed and their quantity is restricted. Therefore . regenerated cellulose and coated cellophane compliant with the EU Directive actually includes a guarantee that exposure to components of coated and uncoated regenerated cellulose at a level of maximum 0.015% in feed does not represent a risk.

3.6.1.4 Aluminium foil

Aluminium divided into small particles will dissolve upon digestion in the gastric fluid and may be absorbed from the GI-tract, although in the gut, due to altered pH and other conditions, some precipitation may occur which could limit the extent of absorption. Absorption of Al from the GI-tract is usually very low (< 1%) but depends greatly upon chemical speciation. A contamination of 0.015% w/w in the feed means exposure to 150 mg Al/kg feed consumed. In the Dutch legislation no SML has been established for aluminium [5]. For human exposure, JECFA (2007) established a (provisional) Tolerable Weekly Intake (pTWI) of 1 mg/kg bw/w, and the same value was reached by EFSA in their evaluation of 2008 (JECFA, 2007; EFSA, 2008). For an adult this would correspond to a maximum level in food of 8.5 mg/kg food. Clearly, based on the pTWI and the anticipated maximum level of Al in feed, a risk for animals cannot be ruled out, especially not if Al would be present in the animal feed at a regular basis, and a further in depth evaluation is necessary to decide if presence of aluminium in animals feed up to the suggested maximum level (0.015 % w/w) is acceptable from a toxicological

[5] Implicitly this means that for Al a maximum migration of 60 mg/kg food is allowed. However, this maximum migration limit is not compliant with the currently adopted (provisional) Tolerable Weekly Intake, and therefore for this assessment, this migration limit is not used for the safety assessment of Al in food or feed.

point of view. Alternatively a lower maximum level of Al in feed may be proposed to guarantee feed safety

3.6.1.5 Printing inks

Taking into account quantity of pigment in a printing ink, the thickness of the printing and the partial coverage of FCM, then pigments and colorants that comply with the German and Dutch legislation will not include a risk hazard. Even pigments and colorants that are not compliant with these rules are not assumed to be of concern.
The printing ink carrier is in general a polymer. The printing is dried thermally to remove solvents like water or organic solvents. In this case the carrier is a polymer which may be even in compliance with Directive 2002/72/EC. Alternatively, some carriers are cured by UV activated initiators. Curing inks may contain still a significant amount of initiators and other reactants and these may be released in the GI-tract.
It is not feasible to make a detailed calculation for individual substances but a general approach shows the following:

> Assume:
> Printing is 5 µm thick = 50 mg/dm²
> FCM is 1 g/dm² and printed for 100%
> Pigment content is 20%; carrier is 75% and additives are 5%.

Feed contaminated with 0.015% w/w of FCM contains 150 mg/kg and when using a film weight of 1 g/dm² the area is 0.15 dm². This means that the total amount of printing ink is 0.15 dm² x 50 mg/dm² = 7.5 mg printing ink in 1 kg feed. It contains theoretically 1.5 mg pigment; 5.63 mg carrier and 0.375 mg additive per kg feed. If the additive concerns a UV-curing initiator of which 50% survives the curing process then the free initiator is 0.19 mg/kg feed. Without any knowledge of the toxicological properties any conclusion will be premature. It is noted that the EFSA has evaluated a few of these type of components (e.g. EFSA opinion on ITX: EFSA, 2005) resulting in a conclusion that the risk is limited, if any. Nevertheless, the presence of printed surfaces needs further attention to evaluate the risk of their presence in FFP-containing feeds. Actually the average printed area of relevant packaging materials should be established. If the average printed area of packaging particle remained in the FFP is less than 10% then the possible risk may be considered negligible.

3.6.2 Physical risks

There have been published a few relevant publications on the physical risks of packaging materials in feed ingredients. Publications, if any, are predominantly found in popular journals. Personal discussions with representatives from companies point to larger plastic fragments and sharp metal particles [6] as main causes of any risk.

Physical damage to the GI-tract can be caused by materials such as soil, sand, grit, glass, metal, plastic. Already in 2001 awareness of the need of limitations existed. Beumer et al. (2001) described tolerance levels for poly-ethylene (0.5% /kg fat) and plastics in general (1% /kg DM). They consider the risk as "low" provided that the particles do not have sharp points, and the occurrence as "moderate". Chemical and toxicological aspects have been more frequently addressed (Munro et al.,

[6] In Dutch: "scherp in", officially indicated as traumatic reticulitis. In this report the word "sharp" will be used.

2002; Barlow, 2009; Lee, 2009). Digestibility of paper and board fibres are considered to be 75-90 % for pigs (Kamphues, 2005).

There is only one exception to this general description of physical risks. Larger particles with sharp edges or points (wire from old tyres used as roughage clamps, fence wires, nails, screws, wire parts from concrete) can cause problems in the GI-tract (traumatic reticulitis; Roth and King, 1991). Ruminants usually swallow their feed without chewing for a first storage and digestion in the reticulum/rumen. The lack of chewing implicates that sharp particles will not be detected easily by the animal. Before the second phase, in which the so-called cud is chewed and prepare for further digestion, the sharp particles can start to penetrate e.g. the reticulum wall. Animals with traumatic reticulitis show a specific pattern of symptoms, including abdominal pain, reluctant to move, standing with arched back, reduced rumen activity and modest fever. The sharp particles can migrate to heart, lungs and liver [15, 16].
Fragments larger than 7 mm with sharp edged or points are generally considered as harmful for animals and treatments have been developed (Cramers et al., 2005). For comparison, particles larger than 2 mm are already considered harmful for children (Beumer et al. (2001). Processing of FFPs usually involves sieving at 1 or 2 mm mesh size. As a consequence, “Sharp” will only occur by incidence in FFPs intended for feeding.

3.7 Risk inventory humans

Transfer of (physical) particles via the GI-tract of animals to their tissues will not occur. Therefore, a risk for human health when consuming animal products caused by a physical injury of animals does not exist (Makkink and van der Poel, 2002). In the remaining presentation of a risk evaluation of remnants of packaging materials in feed for human beings is focused on putative chemical risks.

3.7.1 Chemical risks

Admixture of FFP in animal feed does not result in a direct contact of humans with chemical components in FCM included in these FFP-containing feeds. However, humans may be exposed through foods from animal origin, if the animals have been fed with such feeds. Substances which are absorbed in the animal’s tissues including fat and organs may become part of the human food chain. In addition, human exposure may also result from substances which are secreted in milk or deposited in eggs. Levels of substances in human foods depend on migration characteristics in the GI-tract of the animal and on the toxicokinetics of the substances. Migration behaviour of substances from the FCM into the contents of the GI-tract is important, since it determines the exposure of the animals. The toxicokinetic behaviour of the substances (i.e. their absorption, distribution, metabolism and excretion characteristics) determines the levels of these substances in foods from animal origin. Concentrations of substances (or metabolites) in animal tissues depend on the rate of elimination, which is usually expressed as the “half-life”; the time required to reduce the blood concentration, or the amount in the body or a specific tissue by a factor of two. The shorter the half-life, the less the chance to build-up concentrations of a substance in an animal’s tissue. It may be considered that accumulating substances usually have a lipophilic character which will result in deposition in fatty tissues. Further background information on carry-over and related issues can be found in Leeman et al. (2007), Franz et al. (2008) and van Raamsdonk et al. (2009).

Human exposure depends strongly on the amount of animal products consumed. As a conservative estimate in the evaluation process of FCM, it is assumed that humans can consume approximately 200 g fat per day from all sources. Since fat from animal origin is only part of this, this would limit human exposure to a substance contained in that fat. Consumption of organs will be even much less.
For substances secreted in milk a “dilution factor” can be estimated. If it is assumed that a cow would daily eat 5 kg compound feed containing 50 µg substance/kg feed, while she produces 30 l milk/day on average (Dutch estimations; van Raamsdonk et al., 2007), this animal would be exposed to 250 µg substance per day. If these 250 µg are all excreted via the milk, then the milk will contain (250/30) 8.33 µg/l. This would indicate a dilution factor of six (50/8.33 i.e. ratio of concentration in feed over concentration in milk). In chapter 3.6.1 it has been made conceivable that the concentrations in feed of chemicals present in FCM, will be less than the SMLs after migration or complete release from the FCM. With the dilution factor of six in mind, it may be assumed that concentrations in milk will not exceed the SMLs, either.
Without prejudice to the above, for a thorough analysis of this route of human exposure, detailed information is necessary, and the limited scope of this evaluation only allows a general approach and prohibits a thorough evaluation of this carry-over.
Nevertheless, some general statements can be made, based on data requirements for registration and the authorisation procedure of chemical substances used for FCM manufacture.

3.7.1.1 Plastics

Many substances in FCM production have functional groups in their chemical structure (see substances mentioned in the annexes to Commission Directive 2002/72/EC), which will facilitate their metabolism and elimination, thus reducing chances on accumulation. Also, the degree of any halogenated substances is low, which is also a favourable structural characteristic with respect to possibilities for rapid metabolism and elimination. Chemical substances with different SMLs are discussed below in further detail.

- Substances for which migration is low (SML < 0.05 mg/kg food) would not be anticipated to result in significant accumulation in animal tissues, milk or eggs due to the low exposure to animals. Based on a 0.015% w/w contamination of the feed with packaging materials and the presence of a substance with a SML of 0.05 mg/kg food, the exposure to animals would be 0.5 µg/kg feed [7]. Even for accumulating substances this would not immediately pose a human health risk.
- For substances with intermediate migration, (0.05 mg/kg food < SML < 5 mg/kg food) information is required to evaluate if such substances could have an accumulation potential, which in the current context could also be indicative of significant carry-over to human foods. If accumulation potential is not identified, also no potential for carry-over may be anticipated. In contrast, no authorisation will be granted to intermediate-migration substances with an accumulation potential that cannot be neglected, unless extensive toxicological data are available to make sure that such substances would not pose a health risk.
- For substances with high migration (SML > 5 mg/kg food) extensive toxicity data are required. The data requirements are so extensive that for such substances the possible potential for

---

[7] The SML of 50 µg/kg food is related to a FCM surface area of 6 dm^2, which is equivalent to 15 g of FCM. Since in the feed only 0.15 g FCM/kg is present, this could give rise to a concentration of 0.5 µg/kg feed if migration in feed and in the GI-tract is assumed to be similar to migration in food or food-simulant under conditions in the animal GI-tract.

accumulation is accounted for in the authorisation procedure. If such a substance would have a high accumulation potential in animal-derived food products, for this substance a significant carry-over may be anticipated. It is questionable if such a substance would pose a health risk to humans, taking into account that, given the relatively short life-time of farm animals and the rather low quantities of FCM in the feed, concentrations of such substances in animal-derived foods will be very limited. In addition, it is noted that inherently, high-migration substances will have low toxicity, even when ingested during a whole human life-time.

3.7.1.2 Paper and board

For Paper and board the same may apply as explained above for substances used for the manufacture of food plastics. However, since the information on paper / board chemicals is far more limited this is difficult to substantiate.

3.7.1.3 Aluminium

Very long half-lives for aluminium have been reported in animals and humans (EFSA, 2008), and it cannot be excluded that increased levels in foods from animal origin may be anticipated for aluminium present in animal feed. Whether these levels would result in a significant health risk cannot be assessed at this stage. Aluminium foil can easily be removed in the processing of FFP to animal feed (see Annex 4). The amount of aluminium in feed originating from aluminium-paper or -plastic laminates can be reduced, but such materials are more difficult to remove quantitatively than unlaminated aluminium foil. However, if the total contamination of feed does not exceed 0.015% w/w, than the amount of aluminium in a laminate is certainly less than 0.015% w/w, due to the contribution of paper or plastic.

3.7.1.4 Printing inks

For substances present in printing inks, no evaluation for the potential and consequences of carry-over can be made due to lack of data on toxicity and exposure.

3.8 Risk inventory environment

In this chapter focus is on the risks for the environment of packaging materials in FFPs. The evaluation is specified for arable soils that are fertilized with pig manure from pigs fed with recycled bread and bakery products.
Bread and bakery products are packed mainly in plastics, paper, paperboard, and aluminium.
From these packaging materials plastics probably pose the highest threat for the environment. The other materials used in large quantities, are either of organic origin and rapidly biodegradable (paper, paperboard, regenerated cellulose etc.), or relatively low adsorbent (aluminium will oxidise to Al_2O_3). Therefore, to estimate the risk of food packaging materials for the environment, this chapter is focussed on plastics, more specifically on low density polyethylene (LDPE, [12]).

3.8.1 Assumptions / quantification of the issue

An attempt for a quantitative risk evaluation has been made based on worst case assumptions: the full amount tolerated at an assumed level of 0.15% w/w is occupied by LDPE. The amount of bread and bakery products used for feed production in the Netherlands is estimated at 300.000 MT/yr (see chapter 3.2). It is assumed that 50% of this is packed in LDPE (1.5% w/w), and that a formulation of

10% FFPs in pig feed is applied. Furthermore, for this evaluation it is assumed that LDPE is not degraded or decomposed during its transit through the GI tract of the pigs and will be excreted in manure for 100%. Some calculations can be made on the basis of these assumptions, as presented in Table 6.

Table 6. A quantitative environmental exposure evaluation of packaging materials in FFPs intended for feeding to pigs in the Netherlands.

factor	assumed value	unit	calculated result	unit	ref
amount of bakery products/yr	300000	MT			Chapter 3.2.1
portion packed in LDPE	50	%			
remaining amount LDPE after unpacking	0.15	%			proposed tolerance level
amount of LDPE/yr			225	MT	
share of bakery products in pig feed	10	%			
feed with LDPE/yr			3000000	MT	
total amount of pig feed/yr	6200000	MT			CBS 2009, [17]
total share of pig feed containing LDPE			48.4	%	
excretion of LDPE	100	%			
total production of pig manure	11800000	MT			Meijer et al., 2008
share of pig manure containing LDPE			5709677	MT (wet)	
average amount of pig manure per ha/yr	18	MT			legal limits of P attribution
total area with pig manure containing LDPE/yr			317204	ha	
amount of LDPE per ha/yr			0.709	kg	
amount of LDPE per square kilometer/yr			70.93	kg	

The quantification in Table 6 dilutes the LDPE over all pigs in the Netherlands that are fed on concentrates. Locally, the contamination of arable soils with LDPE may be higher.

Through the nature of the processing techniques used to unpack bread and bakery products, and remix them in the production of concentrates, it is expected that the size of the LDPE particles are smaller then 1 mm^3.

At a density of 0.94 g/cm^3, i.e. 0.94 mg/mm^3, the number of LDPE particles applied to arable soils will be > 7.3 million/km^2 yr.

The degradation time for LDPE in the environment is estimated 10-20 years for plastic bags, and up to 450 years for plastic six pack rings [18].

The environmental degradation of polyethylene proceeds by synergistic action of photo- and thermo-oxidative degradation and biological activity. Since biodegradation of commercial high molecular weight polyethylene proceeds slowly, abiotic oxidation is the initial and rate-determining step. More than 200 different degradation products including alkanes, alkenes, ketones, aldehydes, alcohols, carboxylic acid, keto-acids, dicarboxylic acids, lactones and esters have been identified in thermo- and photo-oxidised polyethylene. In biotic environment these abiotic oxidation products and oxidised low molecular weight polymers can be assimilated by micro-organisms (Hakkarainen & Albertsson, 2004).

Some scenarios are calculated for the steady state levels of LDPE in the environment, based on an annual supply of 70.93 kg/km^2 yr (Table 7). Half-life times of 10, 20 and 50 years are used. The 50 year period for 50% degradation seems to be worst case, but it is included due to the fact that photo-oxidative degradation might hardly occur in soil. Calculations are based on a modified equation as used for exponential transgression of chemical compounds in animals (Franz et al., 2009).

Table 7. Steady state calculations of LDPE in soil for three values of half-life time (top soil level: 0.2 m = 20 cm, amount of top soil = 200.000 MT/km^2).

factor	scenario A	scenario B	scenario C	unit
half-life time of LDPE in the top soil	10	20	50	yr
steady state amount of LDPE in the top soil	1023.34	2046.67	5116.68	kg
steady state reached after	50	100	250	yr
concentration of LDPE in top soil at steady state	0.000512	0.001023	0.002558	%

3.8.2 Risks of LDPE in the environment

Chemical risks: The chemical risks fall apart in two categories: Risks due to added substances to the LDPE, some of which may be toxic, and risks with respect to the chemical nature of LDPE and its degradation products. These aspects are discussed further below. Background information on other sources of plastics in the environment and on exposure to other areas than arable soils are presented in Annex 5.

Additives: Hydrophilic additives may be expected to leach out of the LDPE, after ingestion and digestion in the gastro-intestinal tract of the animals fed with it. These additives may form a risk for the animal, or eventually for the environment when excreted through faeces or urine. Hydrophobic substances may be expected to stay attached or incorporated in the LDPE, and will be excreted with the undigested LDPE in the manure. These hydrophobic additives may pose a risk for the environment when they leach from the LDPE after complete decomposition/degradation. The amount and type of additives is so large and (currently) undefined that a further risk evaluation is not possible within the framework of this study.

LDPE and degradation products: The LDPE itself behaves like a hydrocarbon, the composition of which makes it very resistant to biological degradation. To some extent it might be compared with natural polymers like lignine. Thus the LDPE in manure might be seen as an organic fertilizer with a very slow release of nutrients. The character of these nutrients (alkanes, alkenes, ketones, aldehydes, alcohols, carboxylic acid, keto-acids, dicarboxylic acids, lactones and esters, and up to 200 more constituents; Albertsson & Karlsson, 1988), will be different from those normally recycled to the soil by animal manure, tillage and other organic fertilizers. No studies are found that describe changes in soil biology in response to loading with small particles of LDPE. It is not easy to judge (by best guess) whether such a practice would be beneficial or detrimental.

Physical risks: In the scope of the current study, no plastic particles larger than 1 mm^3 can be expected to originate from FFP used as feed ingredient, due to the nature of the processing techniques

(Annex 4). Therefore, physical risks are not likely to be expected. However it can not be excluded that these small particles may enter the food chain at the level of worms or small insects and could eventually accumulate in the stomachs of specific predators (e.g. birds), posing a threat to their health. To date, no observations are known to substantiate this possibility.

Climate risk: Apart from physical and chemical risks for the soil, the oceans, living micro-organisms, plants and animals, plastics, including LDPE, pose a risk to the biosphere and our atmosphere. Unless recycled completely, LDPE will sooner or later be oxidized to CO_2 and water (Albertsson & Karlsson, 1988; Hakkarainen & Albertsson, 2004). Because the carbon in LDPE originates from oil reserves that are part of the earth's long term carbon cycle, the short term carbon cycle in the biosphere and the atmosphere may become affected with increasing CO_2 levels. Although different in form and purpose, there is no fundamental difference between the use of LDPE as packaging material for food, and our habit to burn mineral fuels, coal, oil and gas to fulfil our energy needs, in that carbon stored in the earth's crust is transferred to CO_2 in the atmosphere (McDonough & Braungart, 2002).

4 Interpretation

4.1 Risk evaluation

The technique called Failure Mode and Effect analysis (FMEA) is frequently used for risk assessment. In the current scope every piece of information that can be included in such an analysis is a rough indication. Therefore, if any FMEA can be worked out, this can only be indicated as a risk evaluation instead of a formal risk assessment, as is indicated throughout this report. FMEA can be used to rank assumed risks, and the assumed values of the different factors can be used as basis for a further discussion and assessment. An individual risk priority number is an indication relative to other RPNs, and an individual value only has any meaning in the framework of the total ranking.

4.1.1 Animal risks

An FMEA is carried out with three factors:

- Frequency of an occurrence on a scale of 0 to 3. Basic data (Dutch): chapter 3.5. Scale:
    - 0: no occurrence.
    - 1: low occurrence (1-10 %)
    - 2: moderate occurrence (11-50 %)
    - 3: high occurrence (51-100 %)
- The level of exposure (severity) on a scale of 0 to 3; the exposure is zero when the value for frequency is zero. Basic data (Dutch): chapter 3.5.
    - 0: no exposure.
    - 1: low average exposure (0.01-0.1 %)
    - 2: moderate average exposure (0.1-0.5 %)
    - 3: high average exposure (> 0.5 %)
- The impact of the effect on a scale of 0 to 3. Basic data: chapters 3.6.
    - 0: no effect.
    - 1: low effect
    - 2: moderate effect
    - 3: high effect

In this initial FMEA each factor was applied with an identical weighing factor. The final risks of a range of causes are calculated by the product of the three values. In this particular FMEA the minimum value is zero (no risk) and the maximum is 27 (highest relative risk).

Table 8. FMEA risk evaluation for animals from several sources related to packaging materials in FFPs.

type	source		Freq.	Exp. level	Impact	Risk
chemical	plastics	monomers	2	1	0	**0**
		fillers	2	1	0	**0**
		additives	2	1	1	**2**
	paper	fillers	3	1	0	**0**
		sizing agents	3	0	2	**0**
		retention agents	3	1	1	**3**
		biocides	3	0	2	**0**
		coating	3	1	1	**3**
	cellulose	softener	2	1	2	**4**
		coating	2	1	1	**2**
	aluminium		2	1	2	**4**
	printing ink	colorants	3 [a]	1	2 [b]	**6**
		carriers	2	1	1	**2**
physical	ferro-metal	small < 2 mm	1	1	1	**1**
	plastic	small < 2 mm	1	1	1	**1**
	any	large > 2 mm	1	0 [c]	3	**0**

Notes: *a) the occurrence of printing inks is related to the presence of paper, since printing inks do not occur without a matrix.*
b) the indication "moderate" is chosen because of the almost absence of any toxicological data.
c) the exposure level is chosen to be zero, because "scherp" does not originate from FFPs due to the strict sieving practice.

Fillers and monomers have either a very low toxicity (e.g. calcium carbonate), or are insoluble and show therefore no transfer to any body part (chapter 3.6.1). Due to these circumstances the effect of these aspects of plastic and paper/board is set at "none". FCMs of food products are accepted only if the absence of sizing agents and biocides is proven, or that their absorption is at a required low level (chapter 3.5.1). It is therefore safe to assume an exposure level of "none".
Considering the situation that in the presented FMEA the highest possible RPN has a value of 27, all risk indications are at a very acceptable level. The highest risks in a relative ranking are:

- Printing inks. The RPN for printing inks is 6, based on a worst case situation. The value for their presence (frequency) is connected to the most frequently occurring matrix, i.e. paper/board, and the poverty of toxicological data indicates the need to pay more attention to this aspect.
- Aluminium is present in FFPs from aluminium trays, foils as well as from a combination with paper (laminated paper). In addition to this, exposure will also occur from the amount of aluminium present in premixes. Absorption is usually below 1 % of the exposure, but depends upon chemical availability and the situation in the GI-tract (chapter 3.6.1.4). The value for exposure is set at 1. The impact can be relatively high due to the long half-life of aluminium in tissues. Due to these uncertainties the impact is set at 2. The resulting RPN of 4 (2 * 1 * 2) indicates the desire to pay further attention to the presence of aluminium in feed. Setting a tolerance limit based on a more detailed risk assessment considering the effect of the presence of packaging materials could be recommended.

- Softeners in regenerated cellulose. As indicated in chapter 3.6.1.3, softeners might have a presence of up to 27 % in RC, and a notable migration limit is set. It is, however, also pointed out in chapter 3.3.4 that RC has limited application as packaging material. However, this limited presence (frequency) can not be based on the general data for occurrence of foreign materials (chapter 3.5), which results in an RPN of 4 (2 * 1 * 2).

4.1.2 Human risks

The relative levels as defined in chapter 4.1.1 can not automatically be used for evaluating the risk for humans. The chance that migration of chemicals occurs from feed to animal products is related to the frequency of occurrence in the feed. However, the exposure level and the final effect also depends on the level of migration of the specific chemical compounds. As pointed out in chapter 3.7, additives with a notable or high migration potential (high SML) are only authorized if a low or very low toxicity (part of the effect) is proven. Therefore, the scales for exposure level and effect as presented in chapter 4.1.1 need to be adjusted with an extra level (rank: 0.5) for very low exposure (low migration) and very limited effect (low toxicity). A first indication of possible ranking of risks is presented in Table 9.

Table 9. FMEA risk evaluation for humans from several sources related to packaging materials in FFPs after transfer from feed to animal products.

type	source		Freq.	Exp. level	Impact	Risk
chemical	plastic/paper	additives high migration	2	1	0.5	**1**
		additives low migration	2	0.5	1	**1**
	aluminium	chemical absorption of Al	1	1	2	**2**

The frequency of occurrence for both paper and plastic is set at 2, which is the scale of the general occurrence of plastic (chapter 3.5). Although paper is assumed to be degraded to a large extent in the GI-tract of the animal, this does not mean automatically that the frequency of absorption and migration to animal products is low. Because of the long half-life time of Al in tissues an RPN of 2 indicates the requirement of further research.

4.1.3 Environmental risks

The basic data for a risk evaluation can only partly be extracted from chapter 3.5. Paper is degraded for the larger part in the GI-tract of animals, which limits the frequency of occurrence in the manure. The frequency of LDPE is based on the general occurrence of plastic in FFPs and on the assumption that no degradation occurs in the GI tract. Furthermore, besides LDPE any estimations concerning additives in other types of plastic and in paper are not made in chapter 3.8. A risk evaluation of some materials that might be present in manure is presented in Table 10.

Table 10. FMEA risk evaluation for the environment from several sources related to packaging materials in FFPs after excretion by animals.

type	source		Freq.	Exp. level	Impact	Risk
chemical	LDPE	additives, contaminants	2	1	1	**2**
physical	LDPE	polymers	2	1	2	**4**
	paper	fibres	1	1	0	**0**
	alu foil	any	1	1	1	**1**

LDPE polymers are assumed to accumulate in the soil due to their long half-life time. Other plastics besides LDPE still need to be considered. They might pose a risk due their low degradability and presence of additives and/or plasticizers (see chapter 3.8.2).

4.2 Discussion

In 2006 an evaluation of the German opinion and reports on the presence of packaging materials in FFPs (see Annex 3) was carried out. A priority list was presented for future research. Several of the proposed activities have been accomplished. The state of expertise can be indicated as follows:

- ⇨ General
  - A first attempt for the quantification and application (e.g. target animal) of the major categories of FFPs for feeding in the Netherlands has been given (chapter 3.2).
  - Major types of packaging materials are presented and discussed (chapter 3.3)
  - A "what-if" analysis of several tolerance levels is presented based on Dutch data (chapter 3.5).
- ⇨ Toxic aspects, risks
  - Animal risks
    - Chemical risks are discussed and evaluated (chapter 3.6.1).
    - Physical risks are discussed and evaluated (chapter 3.6.2).
  - Human risks
    - Chemical aspects are discussed and evaluated (chapter 3.7).
  - Environmental risks
    - An evaluation of chemical and physical aspects is focused on the presence of LDPE in manure of pigs. Other plastics are currently not considered. Although the presence of paper in manure is assumed to be limited, a further evaluation of paper as well as aluminium foil a.o. is recommended (chapter 3.8).
- ⇨ Enforcement aspects
  - A detection and quantification method for foreign materials in bakery products is validated in the Netherlands. Monitoring results for the Netherlands for the period 2005-2010 are evaluated (chapter 3.5). A method for the detection of foreign materials in other categories of products (moist, wet, high sugar content, high fat content, etc.) still needs attention.
  - Methods for the identification of the foreign materials by means of e.g. MS or NMR for confirmation of their nature for being packaging materials need to be developed.
  - Sampling strategies are not evaluated.

⇨ Process control
  - Unavoidable levels of packaging materials in FFPs can be indicated (chapter 3.5). Depending on the type of FFPs, levels ranging from almost zero to 0.05 % w/w are achievable.
  - Several other aspects of processing such as alternative processes (chapter 3.4; Annex 4) or alternative use are only discussed briefly.

⇨ Ethical aspects
  - It is pointed out to find a balance between the desire to keep major amounts of edible products available for consumption and the prevention for animals to consume all kinds of contaminants, including remnants of packaging materials (chapter 3.1). Valorisation should be maximized in the view of a minimal risk.

4.2.1 Animal risks

Use of FFPs in animal feeds, unavoidably will include the presence of small amounts of packaging materials. As the packaging materials have been used for food contact they shall comply with relevant European and national legislation for FCMs. Considering a worst case situation of 0.15% w/w packaging material in the FFP and a maximum share of 10% of FFPs in animal feeds, this results in an amount of packaging material of 150 mg/kg in the animal feed. The major FFP were identified and their packaging materials are discussed to some detail. It appears that there is no apparent health risk to be expected from the used plastics or paper and board. This is supported by calculation for some typical substances. As a result of the FMEA, only the release of substances originating from printing inks, aluminium, or the presence of softeners might raise a risk concern. For these components of FCM further study is necessary to conclude definitively on their risk. The effect of aluminium might need additional attention because of its long elimination half life from animal tissues, e.g. by monitoring its level in feed.

4.2.2 Human risks

The basic conclusion for the large range of chemical compounds present in FCMs is that more strict tolerance limits are required for the level of toxicity when a notable or high migration (SML) is established. In this way the risk is limited either by means of low exposure (migration) or by means of a limited effect (toxicity). For substances migrating from plastics, no health risk for humans is anticipated as a result of migration to animal tissues or products (e.g. milk). The same might be applicable for substances in paper / board. For aluminium and components in printing inks it is not clear if the presence of these substances in animal feed could result in a relevant level of carry-over to foods from animal origin.

4.2.3 Environmental risks

An evaluation of the environmental risk of packaging materials in FFPs used as feed ingredient is a complicated issue. A steady state concentration of 0.003 % LDPE in top soil after a worst case calculation (Table 7) would suggest that a risk is negligible. However, these figures should be considered in a broader perspective. The FMEA (chapter 4.1.3) is developed in a way comparable to those of animal and human risks, and the deposition of plastic via feed and manure should be compared to other sources of environmental pollution (Annex 5).

As shown, an RPN with a value of four for polymers of LDPE suggests that further attention is needed. The scarcity of data for other types of plastic, and of other categories of packaging materials (chapter 3.7), points to the need of further research.
The absolute amount of plastic originating from manure (Table 6: 225 MT/yr) results in a deposition of more than 70 kg/km^2 yr as based on estimations for the Netherlands. Compared to ocean debris (Annex 5: 5.1 kg/km^2 yr) this is a 14 times higher exposure. The marine “plastic islands” are an increasing concern for society (see Annex 5).

5 General conclusions and recommendations

The current report provides a limited risk evaluation, which is based on data from the Netherlands as far as information on use and monitoring of packaging materials is concerned. It is recommended to extend this evaluation to a formal assessment on a European scale. The presented Failure Mode and Effect Analysis (FMEA) gives a first indication of priority ranking of relevant aspects.
The major category of former food products (FFPs) in the Netherlands used as feed ingredient is bakery products which amounts to 300.000 MT/yr. Application is predominantly its inclusion in pig feeds. Confectionary and sweets (in the form of candy syrup) is also applied, the latter as replacement of molasses as ingredient and as a pelleting aid.

The Dutch monitoring program in the period 2005-2010 (243 samples) reveals that on average 0.03-0.06 % w/w of foreign material is found in bakery products (160 samples). These foreign materials consist of fibres (paper/board), plastic, paper laminated with aluminium and aluminium foil. In other categories of FFPs such as cocoa products, sweets and dairy average levels comparable to or lower than those found in bakery products were traced. More than 90 % of all 243 samples showed contamination levels below 0.1 % w/w. The categories sweets and cocoa products accounted for more than half of the approx. 10 % of non-compliant samples (see Table 5). Less than 5 % of the samples in the largest category (bakery products) exceeded the threshold. A “what if” analysis revealed that tolerance levels between 0.1 % w/w and 0.2 % w/w have comparable effects on the number of non-compliant samples. It is recommended to collect data from monitoring programs of other member states. Methods for detection and quantification of foreign materials in other categories of FFPs than bakery products are needed.

Plastic, regenerated cellulose, paper/board, aluminium, ferro-metals and printing inks, including the different added chemical compounds have been presented and discussed. It is concluded that a large range of different additives are allowed according to European legislation. Severe requirements are in force for any acceptance as food contact material (FCM). It is concluded that these measures prevent significant risks when these FCMs enter the feed production chain as contamination of FFPs. The highest Risk Priority Number (RPN) resulting from the FMEA is six on a scale between zero and 27. Risks for animals, for humans by consuming animal products, and for the environment through application of manure as fertilizer of arable land is analysed in more detail:

- Animal risks: the risks with the highest RPN are additives in printing inks, aluminium and softeners in regenerated cellulose. The values for these RPNs are generally caused by a scarcity of relevant data, and therefore need to be marked as highly uncertain. A further risk assessment in the view of the occasional presence of packaging materials, and monitoring of selected compounds (e.g. aluminium) could be recommended. Physical risks are almost absent.
- Human risks: the risks of exposure to FCM chemical compounds via the animal feed route is generally low. The long half life of aluminium in animal tissues is a matter of concern. Physical risks are absent by definition.

- Environmental risks: the risks for the environment are very difficult to specify. The deposition of LDPE as a type of plastic reaches notable levels. It appeared not possible in the framework of this study to establish the risks of other plastics, and other packaging materials in manure to the environment.

It is recommended to assess more thoroughly the level of risk for the aspects mentioned.

On the basis of the evaluation in this study of packaging materials in FFP intended for animal feed, the following four aspects can be considered:

- The evaluated risks are limited; further attention is required for the specific risks as mentioned in the previous paragraph.
- The European Union maintains an extended policy for accepting FCMs.
- Unpacking procedures for FFPs are well established and maintained.
- A tolerance limit higher than zero can sufficiently be monitored by means of the existing control method for the type of FFP with the largest annually produced amount (i.e. bakery products).

Considering these aspects, and in the view of the limitations of the current study, it can be concluded that major animal or human health risks have not emerged from the current evaluation, but that for some (components of) food contact materials only very limited data is available. A tolerance level higher than zero could be acceptable, whereas some aspects need further considerations to conclude a specified value. It may be considered to establish different tolerance levels for the different types of FFPs.

It can be considered a waste of highly nutritional material when FFPs are not used as ingredient of animal feed. An alternative use, such as biofuel production or fermentation, would imply the unavoidable application of other high valued materials, which then will have to be deducted from the food production chain.

6 References

6.1 References

Albertsson, A.-Chr. & S. Karlsson, 1988. The three stages in degradation of polymers—polyethylene as a model substance. Journal of Applied Polymer Science, Volume 35, 1289–1302.

Barlow, S.M., 2009. Risk assessment of food-contact materials: past experience and future challenges. Food additives & contaminants, 26, 12, 1526-1533.

Beumer et al., 2001. Risico-inventarisatie (vochtrijke) voedermiddelen. Fase II. Gevarenidentificatie, risico-inschatting en beheersmaatregelen op het niveau van productgroepen en producten. TNO_Rapport V3437.

BfR, 2009. Recommendation XXXVI. Paper and board for food contact. BfR Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment). Available at: http://bfr.zadi.de/kse/faces/resources/pdf/360-english.pdf (26 Jan 2011).

Cramers, T., K. B. Mikkelsen, P. Andersen, C. Enevoldsen & H. E. Jensen, 2005. magnets in traumatic reticulitis in cows. Veterinary Record 157: 287-289.

Davis, G and Song, J.H., 2006. Biodegradable packaging based on raw materials froms crops and their impact on waste management. Industrial crops & products 23, 147-161.

EFSA, 2005. Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to 2-Isopropyl thioxanthone (ITX) and 2-ethylhexyl-4-dimethylaminobenzoate (EHDAB) in food contact materials. (Question numbers EFSA-Q-2005-240 & EFSA-Q-2005-241), Adopted on 7 December 2005.

EFSA, 2008. Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC). Safety of aluminium from dietary intake. (Question Nos EFSA-Q-2006-168 and EFSA-Q-2008-254) Adopted on 22 May 2008.

European Commission, 2001. Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. OJ L 147, 31.5.2001, p. 1–40 .

European Commission, 2002. Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs. OJ L220, 15-08-2002, p.18.

European Commission, 2002. Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption. OJ L 273, 10.10.2002, p. 1–95 .

European Commission, 2003. Opinion of the Scientific Committee on Food on the tolerable upper intake level of trivalent chromium (expressed in 4 April 2003) (SCF/CS/NUT/UPPLEV/67 Final). Brussels: European Commission, Health and Consumer Protection Directorate-General. Available at ec.europa.eu/food/fs/sc/scf/out197_en.pdf.

European Commission, 2004. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L338, 13-11-2004, p 4.

European Commission, 2007. Commission Directive 2007/42/EC of 29 June 2007 relating to plastic materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs. OJ L172, 30-6-2007, p.71.

European Commission, 2009. Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC. OJ L 299, 14.11.2009, p. 18–54.

European Commission, 2011. Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. Official Journal of the European Union L 12/1, 15-1-2011.

Fix, J.A, 1996. Strategies for Delivery of Peptides Utilizing Absorption-Enhancing Agents. J. Pharm. Sci. Vol. 85, 1282-1285.

Franz, E., P. Römkens, L.W.D. van Raamsdonk and I. van der Fels-Klerx, 2009. A chain modeling approach to estimate the impact of soil cadmium pollution on human dietary exposure. J. Food Protection 71: 2504–2513.

Hakkarainen, M. & A.-Chr. Albertsson, 2004. Environmental Degradation of Polyethylene. Advances in Polymer Science, Volume 169, 177-200.

JECFA, 2002. Evaluation of certain food additives: fifty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Technical report series 913, Geneva, Switzerland.

JECFA, 2007. Evaluation of certain food additives and contaminants: sixty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives. Report of the 67th Meeting, 2006, Rome, Italy. WHO.

Kamphues, J., 2005. Expert report on Foreign Materials in Feedstuffs. Institut für Tierernährung, Hannover, Germany, 26pp.

Lee, K.T., 2009. Quality and safety aspects of meat products as affected by various physical manipulations of packaging materials. Meat science, 86, 138-150.

Leeman, W.R.; Van Den Berg, K.J. and G. F. Houben, 2007. Transfer of chemicals from feed to animal products: The use of transfer factors in risk assessment. Food Addit. Contam. A 24, 1-13.

Makkink, C. & Van der Poel, A.F.B., 2002. Risico's van vochtrijke bijproducten. DLV Adviesgroep NV, Naaldwijk.

McDonough, W. & M. Braungart, 2002. Cradle to Cradle: Remaking the Way We Make Things. North Point Pr.. ISBN 9780865475878. See also http://www.mcdonough.com/cradle_to_cradle.htm.

Meijer, G.A.L., Klein Teeselink, H.; Stroomer, J.C.J.; Ongenae, R.C.J.; Koettner, M., 2008. Strategische verkenning over gisting van mest. Epro Consult, ASG Veehouderij B.V. en HoSt b.v, Lelystad, p. 190.

Munro, I.C., Hlywka, J.J. & Kennepohl, E.M., 2002. Risk assessment of packaging materials. Food additives & contaminants, 19, Supplement, 3-12.

Raamsdonk, L.W.D. van, C.A. Kan, G.A.L. Meijer & P.A. Kemme, 2007. Kengetallen van enkele landbouwhuisdieren en hun consumptiepatronen. Rapport 2007.010, RIKILT, Wageningen, 30 pp.

Raamsdonk, L.W.D. van, G.A.L. Meijer, A.J. Baars, G. van der Heijden, J. Kamp, T. van Aert & J. van der Roest, 2007. Kwantitatieve risico-evaluatie in diervoederketens. Rapport 2007.008, RIKILT, Wageningen.

Raamsdonk, L.W.D. van, J. C. H. van Eijkeren, G.A.L. Meijer, M. Rennen, M. J. Zeilmaker, L. A. P. Hoogenboom & M. Mengelers, 2009. Compliance of feed limits, does not mean compliance of food limits. Biotechnol. Agron. Soc. Environ. 13(S): 51-57.

Roth, L. & J.M. King, 1991. Traumatic reticulitis in cattle: a review of 60 fatal cases. J. Vet. Diagn. Invest. 3: 52-54.

Stamatis, D.H., 2003. Failure mode and effect analysis: FMEA from theory to execution. American Society for Quality, Quality Press, Milwaukee.
WVG, 2010. Commodity Act Packaging and Food Utensils. Regulation of The Netherlands of 20 November 1979 and its amendments up to and including VGP/VC 3000498, April 2010.

6.2 Internet references

[1] Ladder of Moerman:
http://www.minlnv.nl/txmpub/files/?p_file_id=2001236 (22 Mar 2011)
[2] Lansink's ladder:
http://www.eurowaste.be/types-of-waste.shtml (22 Mar 2011)
http://en.wikipedia.org/wiki/Waste_hierarchy (22 Mar 2011)
[3] Failure Mode and Effect Analysis:
http://en.wikipedia.org/wiki/Failure_mode_and_effects_analysis (22 Mar 2011)
[4] http://en.wikipedia.org/wiki/Polyolefins (26 Jan 2011)
[5] http://en.wikipedia.org/wiki/Polyethylene_terephthalate (26 Jan 2011)
[6] http://en.wikipedia.org/wiki/Polystyrene (26 Jan 2011)
[7] http://en.wikipedia.org/wiki/PVC (26 Jan 2011)
[8] http://en.wikipedia.org/wiki/Cellophane (26 Jan 2011)
[9] http://en.wikipedia.org/wiki/Paper_bag (26 Jan 2011)
[10] http://en.wikipedia.org/wiki/Aluminium_foil (26 Jan 2011)
[11] BfR recommendations available at:
http://bfr.zadi.de/kse/faces/DBEmpfehlung_en.jsp?filter=clear (26 Jan 2011).
[12] http://en.wikipedia.org/wiki/Low-density_polyethylene (25 Jan 2011).
[13] http://aluminium.matter.org.uk/content/html/eng/default.asp?catid=172&pageid=2144416566 (3 Mar 2011)
[14] http://en.wikipedia.org/wiki/Fick's_laws_of_diffusion (27 Jan 2011)
[15] Heijmans, J. (www.dierenkliniekdekempen.nl ; 15 Oct 2010)
[16] Verberne, R. (www.verberneboek.nl ; 15 Oct 2010)
[17] http://sanoma.voedingscentrum.nl/artikel5.htm (3 Mar 2011)
[18] http://en.wikipedia.org/wiki/Litter (25 Jan 2011)

Acknowledgements

The authors acknowledge the generous support of the RIKILT colleagues dr. S.M. van Ruth, dr. L. van Ginkel and dr. L. Stolker for carefully reading the draft report.
The scientific research and writing of this report was made possible by a grant of the Ministry of Economic Affairs, Agriculture and Innovation, The Hague.

Annex I Excerpt from Regulation 767/2009/EC

REGULATION (EC) No 767/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 13 July 2009

on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC

ANNEX III

List of materials whose placing on the market or use for animal nutritional purposes is restricted or prohibited as referred to in Article 6

Chapter 1: Prohibited materials

1. Faeces, urine and separated digestive tract content resulting from the emptying or removal of digestive tract, irrespective of any form of treatment or admixture.

2. Hide treated with tanning substances, including its waste.

3. Seeds and other plant-propagating materials which, after harvest, have undergone specific treatment with plant-protection products for their intended use (propagation), and any by-products derived therefrom.

4. Wood, including sawdust or other materials derived from wood, which has been treated with wood preservatives as defined in Annex V to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (1).

5. All waste obtained from the various phases of the urban, domestic and industrial waste water as defined in Article 2 of Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (2), irrespective of any further processing of such waste and irrespective also of the origin of the water.

6. Solid urban waste, such as household waste.

7. Packaging from the use of products from the agri-food industry, and parts thereof.

Annex II Excerpt from letter to Ministry LNV, 2006

Excerpt of the letter of the inspector-general of the Food and Consumer Product Safety Authority (VWA) to the Ministry of Agriculture, Nature and Food Safety (Min. LNV) of 27 September 2006 (in Dutch), indicating the desire to carry-out a risk assessment for the remnants of packaging materials in FFPs of the food production chain.

oplossing zijn.
-Ofschoon in de regelgeving een nultolerantie is opgenomen voor verpakkingsmateriaal, lijkt het wenselijk om, o.a. gelet op onzekerheden over de methode, een tolerantiegrens in te stellen. In navolging op een in Duitsland uitgevoerd onderzoek lijkt een tolerantie van ong. 0,15% redelijk, waarbij ik als aanvulling zou willen meegeven dat er geen zichtbaar verpakkingsmateriaal aanwezig mag zijn.
-Op dit moment is onvoldoende duidelijk in hoeverre bij het hanteren van een tolerantie voor verpakkingsmateriaal er absoluut <u>geen</u> dier- of volksgezondheidsrisico's zijn. Een aanvullende risicobeoordeling lijkt noodzakelijk.

Annex III Risk assessment 2006

The risk assessment below was produced in 2006 in Dutch. The translation to English is made in the framework of the current project.

RISK ASSESSMENT CONCERNING THE PRESENCE OF PACKAGING MATERIALS IN RESIDUES FOR ANIMAL FEED

Risk assessment requested by:	W. Ooms (Food and Consumer Product Safety Authority, Office for Risk Assessment)
Date of request:	05-01-2006
Date of risk assessment:	19-01-2006 *(draft version)* 09-02-2006 *(final version)*
Coordinator:	M.Y. Noordam (RIKILT)
Risk assessment redactor:	L. van Raamsdonk (RIKILT)
Risk assessment reviewers:	H. Bouwmeester (RIKILT), F.X.R. van Leeuwen (RIVM)
Project number RIVM:	V/320110/05/AA
Project number RIKILT:	800 71904 01

Subject

The risks of the presence of packaging materials in residues intended for animal feed.
NOTE: this is not a risk assessment according to the standard definition. The aim of this report is to evaluate a German research report and to provide an initial indication of priorities for policy and research in the area of packaging materials in animal feeds. The information provided here was used to determine the initial standpoint of the Dutch delegation at the meeting of the Standing Committee on the Food Chain and Animal Health on 27 January 2006 in Brussels. The structure (titles of sections) of this report therefore differ from the usual format.

Research question

In order to be prepared for the scheduled discussion in Brussels , the Office for Risk Assessment of the Food and Consumer Product Safety Authority (BuR) requested the RIVM-RIKILT Front Office Food Safety to produce a risk assessment for the tolerance of packaging material in animal feed made from Former food Products (FFPs) from the food and beverage industries. This risk assessment should include a SWOT analysis of the proposal of the German Ministry of Agriculture, *Technisch unvermeidbare Reste von Verpackungsmaterial*, 25 November 2005 (including the report on which it was based: *Expert's report on foreign materials in feedstuffs*, 1 August 2005, Stiftung Tierärztliche Hochschule Hannover).

In addition, the BuR requested that the report should indicate the aspects that are important for policy making which would deviate from the current policy standpoint (zero tolerance) and establish a non-zero tolerance level for packaging material in the corresponding animal feeds.

BuR set the deadline at 24 January 12.00 hours in connection with the scheduled meeting of the Standing Committee.

Conclusions

1) The research of Stiftung Tierärztliche Hochschule Hannover and the recommendations and proposals based on this research were deficient in a number of areas. In particular, the generalisation from two types of products to all residue streams is not acceptable.
2) It is important to first understand the magnitude and destination of the residue streams (especially recalled and over-date products). In case of limited magnitude and good possibilities for alternative use, abolishing the zero tolerance may not be advisable.
3) There is an enormous diversity of products that can be used as a residue stream in animal feed. This makes it difficult to establish general limits. Some types of products (sticky or wet products) may contain levels of foreign components that are a potential risk for animal health and welfare.
4) To reliably determine a tolerable level (thus a non-zero tolerance) of packaging material in animal feeds, much research is needed concerning both the analytical method and the sampling strategy. An important aspect of this research concerns the homogeneity (or lack thereof) of the sample.
5) In the absence of well-founded research and information about industrial processes, chemical and physical risks, environmental hazards, product differentiation and recovery, there are opportunities for the Netherlands to take an initiating/leading role in research (including developing research methods) and policy development.

Introduction

Commission Decision 2004/217/EC regulates the prohibition of the presence of packaging materials, or remnants thereof, in residue streams that can and will be used for animal feed. This decision applies the principle of zero tolerance, so that each occurrence results in a violation. However, it is clear that not all packaging materials from initially packaged residue streams can be mechanically removed from these streams. In Germany in 2005, this finding led to a discussion and to research into preventing the risks of such packaging materials. Ultimately, this led to a request from Germany to the European Commission to apply the ALARA principle – As Low As Reasonably Achievable – (but not actually using this term), resulting in a concrete proposal to allow a limit of 0.15% - 0.20% w/w of packaging material in residues for animal feed.

The aim of this report is to evaluate the background of and reasoning behind this German request. The basis of this report is the literature (report and letters) from Germany (see list of references) and the above-mentioned request of the Food and Consumer Product Authority, as seen in the light of the existing analysis results of RIKILT. In addition, information from internal discussions at the Food and

Consumer Product Safety Authority and a discussion between staff of the Food and Consumer Product Safety Authority and RIKILT (12 January 2005) was used.

Evaluation

The assessment of the Bundesinstitutes für Risikobewertung (BfR) from 25 May 2005 referred to a letter dated 7 March 2005 from the Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz (BMVEL) to Prof. J. Kamphues, which requested an expert opinion about packaging material in bakery products and confectionery. This assessment of the BfR drew conclusions based on a report from Kamphues. However, the report from this researcher that is available in the Netherlands was commissioned by Bundesverband für die Herstellung von Einzel- und Misch-Futtermitteln aus Nebenproducten der Nahrungsmittelindustrie (FAN) and was dated 1 August 2005. The letter from the BMVEL dated 25 November 2005 to the European Commision, which requested a tolerance level of 0.15% - 0.20%, referring to the first version of Kamphues' report (which stated that FAN commissioned the report and was dated 14 February 2005) and to the assessment of the BfR dated 25 May 2005. Because the opinion of the BfR was based on a version of Kamphues' report from before 25 May, it should be concluded that formally we are not familiar with the basis of the German standpoint (i.e. the first version of Kamphues' report), and that we do not know how it differs from the second version (from 1 August 2005), which we used in this assessment. Moreover, the BMVEL and the BfR referred to differing commissioning clients in their letters/opinions for what we believe is probably the same research.

The three components of the standpoint of the Member State of Germany (the report, the advice of the BfR and the letter from BMELV) are addressed in the following three sections. After this, a number of elements from the text are subjected to a SWOT analysis.

Research conducted by the Stiftung Tierärztliche Hochschule Hannover (Prof. Kamphues)

The research on which the report is based appears to have been properly conducted. The material used consisted of three samples of bread meal (bakery product) and three samples of chocolate (confectionery), with three repetitions for each sample. The material was extensively analysed, including analysis of toxic substances, analysis of production lines at companies and analysis of foreign components (metal, paper, cardboard, stones, etc.). The proportions of foreign components in bread meal are comparable with our findings in the Netherlands: 0.008 – 0.096%. The results for chocolate are somewhat higher (approximately 0.13%). This could be due to the fact that confectionery is packed in smaller units, resulting in more packaging material per quantity of product.

Several aspects from the report will be addressed in more detail below. These aspects are: the homogeneity of the samples, chemical and physical aspects of toxicity, recovery, the relationship between foreign components and packaging material, and the conclusions of the report.

Homogeneity of the samples. In some cases, a large difference between the three repetitions per sample was reported. This indicates that the samples were not homogeneous. The largest difference between the repetitions for a single sample of bread meal amounted to a factor of 12 (a range of 32.7 –

374.4 mg plastic/kg bread meal) and with the chocolate products a factor of 229 (a range of 13.3 – 3054,4 mg plastic/kg product).

Toxicity. Research was also conducted to the occurrence and quantities of heavy metals, mycotoxins, dioxins and microbiological contaminants. Of the product-foreign materials, only the ash, organic matter, iron (Fe) and aluminium (Al) were measured. It is not entirely clear why heavy metals and dioxins were studied. No research was conducted into other toxic substances (preservatives or binding agents in paper/cardboard, plasticisers in plastic) or combinations (plastic coatings on the inside of packaging for liquid products) that could be related to packaging materials (for example, the recent incident with ITX from inks). The diffusion of plasticisers from plastic particles could cause them to become physically hard or sharp, which can injure the gastrointestinal canals of animals.

Recovery. An important aspect was missing: no research was conducted into the level of recovery. For this purpose, research into samples with a known content of the material being studied is required. If the recovery in a product is known approximately, a correction can be applied for this percentage, which causes the results to be higher. The recovery probably depends on the type of product. In his discussion, Kamphues briefly emphasised this point: he expected that it would be somewhat more difficult to remove foreign components from chocolate (sticky material) than from bread flour (dry material). It can therefore be expected that the recovery will probably be lower as well.

Relationship of foreign components and packaging material. To the halfway point in the discussion, the author referred to foreign components, but then changed terminology and referred to packaging material for the second half of the discussion. In view of the research question, this is understandable. However, in the real world it is not as easy to make this shift. In practice, it will be important to show a tenable (legally testable) relationship between the foreign material and the packaging material.

There are three possibilities to link the foreign material (plastic, glass, paper, etc.) to the packaging material:

- by documenting the initial material with photographs, which can be compared with foreign components (if any).
- by also sampling the initial material and the finished material (the product after processing). Chemical or physical analyses, such as NMR, can be used to ascertain the similarity of both materials.
- by administrative monitoring. If it can be ascertained that a single residue stream (such as bread packaged in plastic) enters a purification line, only plastic can emerge as a foreign component, and any plastic that is found is automatically assumed to be packaging material.

The report provides no indication of the possible origin of the foreign materials found. The bakery material concerns three samples of breadcrumbs, for which it is not reasonable that this product would also contain aluminium packaging material, in addition to the logical findings of plastic and paper. The results of an administrative audit to obtain more information about this aspect were not reported. In some cases, many stones were found. The "miscellaneous" category was not defined in detail.

Conclusion of the author of the study. In the second part of the conclusion, a global, qualitative risk estimate was provided with the given contamination levels. This risk estimate referred to the following:

- Plastic: the risk is low, but depends on the size and shape of the material. For example, 0.1% contamination with small plastic fragments is not a problem, but 0.1% with an entire plastic sack is a problem.
- Metal: this is usually not a problem, because much of the metal can be removed with magnets. Consequently, the author reported very low levels of metal contamination. However, many metals are not magnetic.
- Paper and cardboard: these components are highly soluble in the gastrointestinal canal (stomach acid, enzymes). Low levels actually increase the nutritional value (crude fibre).
- Dyes on the foreign components: it was assumed that these dyes had been properly tested, because the residue streams were from products for human consumption. Wrappers for chocolate bars, bags for sweets, etc. must be printed with dyes that cannot easily dissolve or be released by licking or sucking (children!). For a residue stream, it would theoretically no longer be a problem. However, when assessing packaging material, it is assumed that substances and dyes on the outside of the packaging will not come into contact with the food. Consequently, for these substances good toxicity data are usually not available. In addition, following consumption of packaging material as a foreign component in animal feed, digestion processes in the gastrointestinal canal can possibly result in systemic absorption of these substances or dyes, and therefore to possible toxic effects.

The author recommends that the prohibition on the use of packaging material should be maintained in order to counteract abuse (deliberate addition of packaging material). For contamination of other products, where after separation only traces of packaging materials are present as foreign components, he would allow a tolerance of 0.125% w/w. In a previous study, (2003-2004), out of a series of 39 samples, 9 exceeded this level. The fact that the author knew nothing about recovery would certainly affect his conclusions. If a recovery correction were applied, it is possible that many more samples would have exceeded this limit.

Advice BfR, 25-5-2005

The description of Kamphues' research in this advice is largely identical to the research described in the report used here. The BfR concluded that the contaminants in the bread flour and the chocolate products constitute no demonstrable risk to animal welfare, animal production and health. Given the particle size (<0.5 mm), the Germans assumed that the contaminants would pass unhindered through the gastrointestinal tract.
However, the 1 Augustus 2005 version of Kamphues' report stated, “Because of the size and structure of the particles found, a quick passage through the digestive tract can be expected” (page 25), but did not mention that the particles were smaller than 0.5 mm. Contamination in the range of 0.15 – 0.20% w/wis generally assumed to be unavoidable, but Kamphues advised a limit of 0.125% w/w.

Letter from the Bundesministerium VEL to the European Commission, 25-11-2005

This letter referred to a study (the study?) of Kamphues, reported on 14-2-2005, which concerned packaging material in bakery residues. It was stated that a contamination level of 0.15% is unavoidable. Then, based partly on the advice of the BfR dated 25 May 2005, it was stated that levels from 0.15 to 0.20 % w/w are acceptable. Finally, following generalisation, a statutory limit in the EU for contamination with packaging material of 0.15% w/w by weight was proposed.

SWOT analysis

Regarding Kamphues' research and the advice and proposals based on this research, the following aspects can be referred to in a SWOT analysis:

- Strengths:
  - Good summaries of the industrial processes for removing foreign material from products were provided.
  - It was shown that various types of products (dry, fatty and/or sticky) have various degrees of difficulty regarding the removal of foreign components.
  - Between the reported study (2005) and a previous study (2003-2004), the industry apparently made progress in purifying residue streams.
- Weaknesses:
  - The report provided no indication of the possible origin of the foreign material found in products. The results of an administrative audit to obtain more information about this aspect were not reported.
  - Not all metals can be removed with magnets (such as remains of aluminium cans).
  - In some cases, there was a large deviation between the three repetitions per sample. This indicates that the samples were not homogeneous, which has consequences for the interpretation of the data. This is certainly the case with a quantitative analysis, where correct sampling and homogeneity are important.
  - No research was conducted into the presence of toxic substances in the foreign materials in the products, such as preservatives in paper/cardboard, plasticisers and dyes in wrappers, nor was any attention paid to this topic.
  - The possibility that foreign components in products could undergo physical changes and could then become hazardous (for example, the effects of intestinal perforations on animal health and welfare) was not discussed.
  - Following research into bakery products (bread meal only) and sweets (chocolate products), conclusions were drawn that were generalised for all packaging materials in all residue streams. This generalisation appears not to be justified.
- Possibilities/opportunities:
  - Research into the processing chain, the processes and the companies can lead to the conclusion that the magnitude of the residue streams is small and that alternative applications are realistic. Moreover, alternative processes can lead to lower levels of packaging material.
  - Research into inspection of samples could provide insight into the efficiency of isolating foreign material for the inspection. As a result, the recovery per product type could be determined.
  - Due to the lack of well-founded research into toxic effects, physical dangers and product diversity, and the lack of contamination limits based on this research, the Netherlands as EU Member State could quickly take a leading position in this area by conducting research and developing policy.
- Threats:
  - There is an enormous diversity of products that can be used as a residue stream in animal feed. This makes it difficult to establish general limits. In Kamphues' research and the advice of the

BfR, only two types of products were examined. Moist, wet and fatty products will lead to other research methods.

- Because residue streams unavoidably contain some packaging material, it is tempting to apply the ALARA principle based on the technical possibilities for each type of product. Consequently, for some types of products it is possible that limits would be established which would put animal well-being and/or health under pressure.

Current state of affairs in the Netherlands

Since October 2005, as commissioned by the Food and Consumer Product Safety Authority, RIKILT has been investigating residue streams for the presence of packaging material. As of 9 January 2006, 57 samples had been studied, of which 18 yielded negative results. In addition, five samples contained levels of foreign components higher than 0.1% w/w. The results from these five samples are shown in the table below. The other samples contained levels of foreign components ranging between 0.01% and 0.08% w/w.

The 18 samples in which no packaging material was found included bakery products (nine samples, including bread flour), animal fats (6 samples) and chocolate (1 sample). In view of Kamphues' research, which demonstrated that fatty and/or sticky products (chocolate) are more difficult to purify, it can be assumed that these products (or a portion thereof) had never been packaged.

Product	Date of arrival RIKILT	Result
Sweet mix	27-10-2005	Aluminium foil and paper residues 0.7% w/w
Animal feed sweet syrup	10-11-2005	Aluminium foil and paper residues 0.4% w/w
Animal feed bread meal	11-11-2005	Paper residues, aluminium foil & plastic 0.2 % w/w
Sweet syrup	22-12-2005	Paper residues 0.3% w/w
Sweet syrup	22-12-2005	Paper residues 0.7 % w/w + 1.8 % sand

If the ascertained levels of paper/cardboard in sweets syrup cannot be reduced through further optimisation of purification processes, and a limit is nevertheless established by application of the ALARA principle, this could be in conflict with animal health and welfare requirements.

Priorities for policy and research

Following a policy request, a number of brief brainstorming sessions took place at the Food and Consumer Product Safety Authority. These resulted in a list of points of attention which should be taken into account when making policy decisions about establishing a non-zero tolerance for the presence of packaging material contaminants in animal feed. The topics on the list concern animal health, animal welfare, public health, ethics, the environment, enforcement and economic aspects. The topics on the following list are not shown in order of priority:

- ⇨ General
  - Research the magnitude of the residue streams of recalled and over-date products; classifying them according to use (animal feed, methane digestion, composting, incineration) and according to those produced domestically and those that are imported. As the magnitude of the use for animal feed declines, the necessity to establish a non-zero limit also declines.
  - Determine the consequences of a non-zero limit (enforcement, analytical methods).
- ⇨ Toxic aspects, risks
  - Public health
    - Chemical aspects: inks, plasticisers for soft plastics, binding agents for cardboard, heavy metals, etc.
  - Animal health and welfare
    - Physical aspects: perforation of gastrointestinal wall by sharp particles; risk of formation of hard or sharp objects in the gastrointestinal canal (diffusion of plasticisers from plastic)
    - Physical aspects: blockage caused by large/elongated objects
    - Chemical risks as described above
  - Environmental aspects
    - Animal manure containing undesirable substances will be used as fertiliser; as a result, these substances will contaminate the environment. This risk also applies to alternative applications such as composting and methane digestion
  - The effect of particle size, particle shape and the variation in size and shape: smaller particles generally have a lower physical risk, but a higher chemical risk (larger surface area leads to more diffusion)
  - Chemical risks are poorly understood: research is required into the uptake, transmission, excretion and toxicity of undesirable substances such as inks, preservatives, binding agents, heavy metals and phthalates
- ⇨ Enforcement aspects
  - Sampling method: the sample must be representative for a batch and must be homogenous
  - Develop analytical methods for physical and chemical detection (screening), depending on the matrix-substance combination (dry, damp, wet, sugar content, fat content, etc.; plastic, metal, glass, etc.; but also ink, phthalates, etc.)
  - Research into identification (MS, NMR; confirmation): compare the profile of foreign components with known packaging materials
  - Quantification is essential when establishing a non-zero tolerance. This places heavy demands on the detection methods (such as research into recovery)
  - Research into the discriminating capacity of the analysis (limit of detection)
  - Distinguishing capacity of inspectors regarding the recognisability of foreign components
- ⇨ Process control
  - Possibilities of administrative documentation of processes and materials
  - Survey other processes, besides the use of recalled and over-date products, that can lead to problems with packaging or container residues in animal feed
  - Conduct research into the possibilities of eliminating physical/chemical hazards; ascertain unavoidable levels (see PDV letter)
  - Economic effects of purification: yield compared to costs, including non-material effects (for example, much more waste when residue streams can no longer be used for animal feed)
- ⇨ Ethical aspects
  - Societal acceptance of feeding packaging material to production animals

Conclusions

In the German proposal, a number of ideas and basic assumptions were formulated, but these must be worked out in greater detail. If the residue stream of recalled and over-date products for use as a raw material in animal feed is small, then there will not be an urgent necessity to establish a non-zero tolerance. During this process, other forms of packaging materials or containers from other processes (rejected products in drums, Category 3 animal products in barrels for fat rendering, etc.) should not be disregarded.

When establishing a non-zero tolerance for all or some products, more demands must be placed on the sampling strategy (samples must be representative and homogeneous). Moreover, more efforts must be placed to develop detection methods, due to the need for quantification. Much more must be known about the recovery, limit of detection and confidence interval per type of product (dry, sticky, fatty, moist, fluid, etc.) and per type of contamination (paper/cardboard, glass, metal, plastic, etc.). This requires a significant amount of additional research.

With a sufficient magnitude of the product streams, research should be conducted into the uptake, transmission, metabolism, excretion and toxicity of chemical substances from foreign components (plasticisers, inks, preservatives, etc.) regarding risks for animal welfare, animal health, human health and environmental contamination. In addition, research is urgently required into physical hazards and the possibility that foreign components could become physically hazardous (hardening of plastics). In addition, based on an analysis of purification lines, the reasonableness of specific tolerance levels must be ascertained in order to apply the ALARA principle. In short, there are many aspects for a risk analysis. In fact, we should refer to a number of risk analyses, because the topic is very wide-ranging.

References (in chronological order)

Stellungnahme zur gutachtligen Stellungnahme zu Fremdbestandteilen in Recyclingfuttermitteln (gewonnen aus der Verarbeitung von Brot-/Backwaren bzw. Süßwaren). BfR, 25-5-2005. Including English translation.

Kamphues, J., 2005. Expert's report on foreign materials in feedingstuffs made from byproducts of the manufacture of breads/baked goods and confectionary. Stiftung Tierätzliche Hochschule Hannover, 1-8-2005.

Voorschriften t.a.v. verpakkingmaterialen in diervoeders. Brief van PDV aan de Minister van Landbouw, Natuur en Voedselkwaliteit, 10 August 2005.

Technisch unvermeidbare Reste von Verpackungsmaterial. Brief Bundesministerium VEL aan Europese Commissie, 25-11-2005. Including English translation.

Annex IV Overview processing technologies

Overview of several processes which can be applied to treat and separate former foods and packaging materials.

A. Pre-treatment processes.

Process	Description	Applied on:
Coarse grinding	The product to be unpacked will be coarsely ground or cut as a first step to separate product and packaging material.	Bread Cookies Sweets Bakery ingredients
Drying	Often used as an intermediate step in the process of unpacking former foods. The separation of remnants of packaging materials from dried former food products is often easier than from moist or semi moist products.	Bread
Crushing, rolling	Coarse breaking of hard materials such as can, glass and disposable bottles with liquid materials inside. The packaging materials will be separated by means of settling (during different phases) and sieving (max 1 mm). This methodology is also applied to dry dairy products (milk powder; baby foods). Through several sieving steps (max 0.5 mm) the product is cleaned of possible particles of packaging material.	Former foods (liquids) in can, glass or disposable bottles
Dissolving	Solvable former foods (especially sweets) will be dissolved in water (eventually in combination with heating).	Sweets
Squeezing	Flattening of soft packaging materials (packs, cartons, pet bottles, disposable bottles, plastic beakers, …). After squeezing out, its contents will be sieved (1 mm) to separate the packaging material. This technique is also suitable to empty drinking cans.	Dairy products Fruit juices Beer Soft drinks

B. Separation processes.

Process	Description	Applied on:
Sieving (different types)	Separation of packaging materials on the basis of particle size and density Sieving can also be applied after dissolving in water.	Bread Cookies Bakery ingredients Former canned foods Glass and disposable bottles sweets dissolved as syrup
wind sifting or Air classification	Suck off or blow away of packaging materials. With air, materials of different density can be separated.	Bread Cookies Bakery ingredients
Magnet	Separation of ferrous-metals.	Bread Cookies Bakery products
Eddy current separation [13]	Separation of non-ferrous metals (such as aluminium) by using an electric magnetic field.	Bread
Centrifugation	Separation on the basis of density by spinning at a large speed.	Wet products
Separating	With a so-called ‘separator’ , former foods will be separated from packaging materials on the basis of different consistency of the products.	Pastry, cookies, Former foods in soft packaging materials

C. Additional processes.

Process	Description	Applied on:
Manual monitoring (conveyor belt reading)	Unpacked materials are being monitored visually when passing on a conveyor belt. Manually separation of remaining packaging material.	
Manually unpacking or emptying	Manually unpacking or emptying.	Applied to all packaging materials, usually large packages (> 10 kg), buckets, baby foods, etc.

Annex V Additional information on environmental issues.

The environmental pollution from plastics is an issue that gains attention on a global scale. The pollution is a problem on a physical, as well as a chemical, and a biological scale. Moreover, the use of plastics adds to the climate change. The loss of plastics to the environment seems to be rather irreversible, as can be learned from the current concern about the 'plastic soup' in our oceans. The results of plastic contamination of the environment from this study are summarized in Table A.

Table A: Loss (MT/yr), and concentrations (kg/km^2) of plastic in the environment.

		Loss/supply (kMT/yr)	Concentration (kg/km^2)	Reference
Current evaluation	Arable soils (NL)*	0.225	>70**	
Literature evaluations	Recovered from roads	72	-	extrapolated from [6]
	Recovered from cities	80	-	[8]
	Recovered from beaches	15 - 23	-	extrapolated from [9]
	Marine debris (1999)	10000	5.1	[3, 4]

* *from FFPs in feed only*

** *this 'concentration' is added on a yearly basis, the decay is at least 10-20 times less*

In the Netherlands, no monitoring data are available on the true losses of plastics to the environment. Information on some specific situation is presented in the following paragraphs. It is not easy to foresee how these contaminations can be recovered in the future, what the fate of these plastics will be, nor their effects on the ecosystem. Compared to these losses, the amount of plastic that is added to our arable soils, due to recycled food items in pig feed, is relatively small (225 MT on a yearly basis as a worst-case estimate; chapter 3.7). However, the area is comparably small. Compared to the worrying concentrations of plastic debris in the oceans (in the range of 5-10 kg/km^2), the amount added to (40% of) our arable soils (70 kg/km^2 yr) is larger. It is not known whether these plastic 'fertilizers' are beneficial or detrimental for our arable soils, its ecosystem and its future fertility.

Production and use of LDPE

The most common use of LDPE is in plastic bags. Further it is widely used for manufacturing various containers, dispensing bottles, wash bottles, tubing, for computer components, and various moulded laboratory equipment. Other products made from it include [1]:

- Trays and general purpose containers
- Food storage and laboratory containers
- Corrosion-resistant work surfaces
- Parts that need to be weldable and machinable
- Parts that require flexibility, for which it serves very well

- Very soft and pliable parts
- Six pack rings
- Juice and milk cartons, whose "cardboard" is actually liquid packaging board, a laminate of paperboard and LDPE (as the water-proof inner and outer layer), and often with of a layer of aluminium foil (thus becoming aseptic packaging)
- Parts of computer hardware, such as hard disk drives, screen cards, and optical disc drives
- Playground slides
- Plastic wraps

In 2009 the worldwide LDPE market reached a volume of 22.2 billion US-Dollars (15.9 billion Euro)(1). At a price of 2240 $/T [2], this equals a volume of 9,9 Million MT/yr, i.e. $9.9 * 10^9$ kg/yr. This equals approximately 5-10% of the overall production of plastics, which is estimated at 100 - 200 Million MT/yr [3].

LDPE is defined by a density range of 0.910 – 0.940 g/cm³ [1]. At 0.94 g/cm3, the yearly volume of resin produced equals $9.9/0.94 * 10^9 = 10*10^9$ L, i.e. $10*10^6$ m^3.

Loss of plastics to the environment

The spreading of plastics in the environment has recently grown to worrying levels. It is estimated that 10 Million MT/yr of plastics end up in the oceans, of which 20% originates from ships and oil platforms, yet 80% is believed to come from runoffs and urban wastes [3]. Ocean litter – also commonly referred to as “marine debris” – is a persistent and growing problem worldwide. Scientific research demonstrates that debris in the oceans is increasing at an alarming rate: plastic debris in an area north of Hawaii known as the Northwest Pacific Gyre has increased 5-fold in the last 10 years. In this area, in 1999, plastic abundance was 335,000 items/km^2 and 5.1 kg/km^2 [4]. In the Southern Ocean, the amount of plastic debris increased 100 times during the early 1990s. These are just a few examples of the recent marked increase in marine debris. Researchers estimate that 80% of marine debris comes from land-based sources, particularly trash and plastic litter in urban runoff, and the generation of trash and waste is increasing [5].

The amount of waste and litter spoiled to the environment in the Netherlands is not monitored in a general way [11].
The areas where litter is specifically recovered in the Netherlands include roads and highways, communities, and beaches. The amount of litter recovered along 125 km of highway in the IJsselmeerpolders (The Netherlands) amounts to 900 MT/yr [6]. The total length of roads and highways in the Netherlands is 10.000 km [7]. Thus the amount of litter, potentially recovered, along all roads can be estimated to be 72.000 MT/yr. (Only part of these are plastics [10]). The Dutch Communities recovered 20.000 MT of plastics from their area in 2009. Due to increased effort it is expected this will be 80.000 MT in 2010 [8]. The total cost for cleaning cities and roads from litter and debris is over 250 million €/yr in the Netherlands [7]. On one summer day 25 MT of litter are recovered on the beaches of The Hague [9]. Estimating this as approximately 10% of the Dutch beaches, and given 60 - 90 summer days a year, this adds up to 15.000 – 23.000 MT/yr. Thus, a first estimate of the litter recovered from these three types of areas in the Netherlands adds up to 175.000 MT/yr. This figure probably underestimates the true spoilage to the environment, because a) recovery

by cleaning is not 100%, b) not all areas are included, c) also on winter days litter will be spoiled, etc. Therefore it is not known how much litter will remain and decompose (or not) in the environment.

Fate of plastics and LDPE in the environment

Plastic litter in the ocean disintegrates through photo degradation into ever smaller pieces while remaining a polymer. This process continues down to the molecular level, leaving a 'plastic soup'. Ultimately, the polymer molecules become small enough to be ingested by aquatic organisms which reside near the ocean's surface. Plastic waste thus enters the food chain [4].
Some plastics decompose within a year of entering the water, leaching potentially toxic chemicals such as bisphenol A, PCB's and derivatives of polystyrene [4].
Studying the degradative conversion of ^{14}C present in low density polyethylene (LDPE) film to respiratory $^{14}CO_2$ during a 10-year aerated cultivation with soil, and samples exposed to UV irradiation for 0, 7, 26, and 42 days, it was found that LDPE is degraded to CO_2 by three stages up to the final collapse of the structure [12].

Actual developments

Global ban on plastic bags
Because of the environmental and climate risks, plastic bags are now prohibited in several parts of the world. Plastic bags are banned and taxed in South Africa and Ireland since 2003 [13], this trend was followed by China in 2008 [14], Australia, Bangladesh, Alaska and San Francisco [14]. Currently a ban is considered in California, New York, other US states and other countries worldwide [13, 14, 15], as well as by Wall mart, a large grocery firm in the US [15]. It is estimated that the ban in China saves 37 million barrels of oil on a yearly base [16]. Thus there is a growing development of banning the use of plastic bags worldwide, that may be foreseen to expand to more and more countries and more plastic packaging utensils in the future.

Cleaning plastic from the oceans
So far, nations have not felt responsible for the marine debris in the oceans. Yet, there is a huge amount of ideas and initiatives from private companies and NGO's aimed to clean the oceans. Amongst these are 'the recycled island' [17], and a 'recycled plastic vacuum cleaner' from the sea [18].

Increasing the biodegradability of plastics
The biodegradability of plastics can be improved by several additives. For example, enhanced environmentally degradable polyethylene is prepared by blending with biodegradable additives or photo-initiators or by copolymerisation [19]. Although this will increase the rate of degradation in the environment, it will not solve the climate effects related to the source of the polymers, i.e. mineral oil. Rather, to the contrary, it will accelerate the release of CO_2 to the atmosphere.
A different development is that of biodegradable plastics (polymers) from organic, e.g. plant, origin. These 'plastics' are currently available in many types and forms. Most of the applications of traditional plastics can now be replaced by these organic degradable plastics, and their use is increasing, for example in car building, packaging, etc. For many applications, the organic plastics still have a higher cost.

References

[1] http://en.wikipedia.org/wiki/Low-density_polyethylene

[2] http://www.designerdata.nl/index.php?

[3] http://pacificoceanplasticfree.com/cms/index.php?page=Facebook

[4] http://en.wikipedia.org/wiki/Great_Pacific_Garbage_Patch

[5] http://www.opc.ca.gov/tag/marine-debris/ ; http://en.wikipedia.org/wiki/Marine_debris (26 Jan 2011)

[6] http://en.wikipedia.org/wiki/Litter (25 Jan 2011)

[7] Anonymous, 2010. Rapport kostenonderzoek zwerfafval Nederland. Deloitte, Den Haag.

[8] Letter from the VNG to the permanent committee VROM of the Dutch Parliament addressing the general meeting of 23 March 2010 concerning waste and packaging materials.

[9] http://www.honderdprocenthaags.nl/nieuws/tonen.php?datum=20100716&item=450

[10] Gutter, N., 2005. Zwerfafval en Verpakkingsontwerp. Duuraamheidswinkel Amsterdam/TU Delft.

[11] Anonymous, 2008. Nederlands afval in cijfers: gegevens 2000-2006. SenterNovem Uitvoering Afvalbeheer, Utrecht. 166 p. ISBN 978-90-5748-065-2.

[12] Albertsson, A.-Chr. & S. Karlsson, 1988. The three stages in degradation of polymers—polyethylene as a model substance. Journal of Applied Polymer Science, Volume 35, 1289–1302.

[13] National Geographic News, April 4, 2008. Plastic-Bag Bans Gaining Momentum Around the World (http://news.nationalgeographic.com/news/2008/04/080404-plastic-bags.html).

[14] New York Times. China bans free plastic shopping bags, 9 January 2008. (http://www.nytimes.com/2008/01/09/world/asia/09iht-plastic.1.9097939.html).

[15] Laist. California Plastic Bag Ban Approved by Senate Environment Committee, 28 June 2010 (http://laist.com/2010/06/28/california_plastic_bag_ban_approved.php).

[16] The Daily Green. China's Plastic Bag Ban Will Save 37 Million Barrels of Oil, 1/9/2008 (http://www.thedailygreen.com/environmental-news/latest/china-plastic-bags-47010907).

[17] Erne, E. Recycled Island: Cleaning our Oceans and Creating a Floating City, Stichting milieunet, Afval en Cradle to cradle, 14/4/2010 (http://www.stichtingmilieunet.nl/andersbekekenblog/duurzaam/recycled-island-cleaning-our-oceans-and-creating-a-floating-city.html).

[18] Design for Good, Bigthink.com. Cleaning Up the Oceans with a Vacuum Cleaner, Nov. 2010 (http://bigthink.com/ideas/24814).

[19] Hakkarainen, M. & A.-Chr. Albertsson, 2004. Environmental Degradation of Polyethylene. Advances in Polymer Science, Volume 169, 177-200.